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DEPT OF COURT RECORDS
CIVIL FAMILY DIVISION
ALLEGHENY COUNTY PA

IN THE COURT OF COMMON PLEAS OF ALLEGHENY COUNTY, PENNSYLVANIA
CIVIL DIVISION

COVER SHEET

Plaintiff(s)

ALLEGHENY COUNTY POLICE ASSOCIATION

Vs

Defendant(s)

COUNTY OF ALLEGHENY, PENNSYLVANIA

Case Number : GD-21-012665

Type of pleading :

COMPLAINT IN EQUITY SEEKING PRELIM. & PERMAN. INJUNCTIONS

Code and Classification :

Filed on behalf of

ALLEGHENY COUNTY POLICE ASSOCIATION

(Name of the filing party)

☑ Counsel of Record

☐ Individual, If Pro Se

Name, Address and Telephone Number :

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14 October 2021
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GD-21-012665

Supreme Court of Pennsylvania

Court of Common Pleas
Civil Cover Sheet

Allegheny County

For Prothonotary Use Only:	
Docket No:	

The information collected on this form is used solely for court administration purposes. This form does not supplement or replace the filing and service of pleadings or other papers as required by law or rules of court.

SECTION A

Commencement of Action:
☒ Complaint ☐ Writ of Summons ☐ Petition
☐ Transfer from Another Jurisdiction ☐ Declaration of Taking

Lead Plaintiff's Name:	Lead Defendant's Name:
Allegheny County Police Association	County of Allegheny, PA
Are money damages requested? ☐ Yes ☒ No	Dollar Amount Requested: (check one) ☒ within arbitration limits ☐ outside arbitration limits
Is this a *Class Action Suit*? ☐ Yes ☒ No	**Is this an *MDJ Appeal*?** ☐ Yes ☒ No

Name of Plaintiff/Appellant's Attorney: Ronald R. Retsch, Esq. & Welby, Stoltenberg, Cimballa & Cook, LLC

☐ Check here if you have no attorney (are a Self-Represented [Pro Se] Litigant)

SECTION B

Nature of the Case: Place an "X" to the left of the **ONE** case category that most accurately describes your ***PRIMARY CASE.*** If you are making more than one type of claim, check the one that you consider most important.

TORT *(do not include Mass Tort)*
- ☐ Intentional
- ☐ Malicious Prosecution
- ☐ Motor Vehicle
- ☐ Nuisance
- ☐ Premises Liability
- ☐ Product Liability *(does not include mass tort)*
- ☐ Slander/Libel/ Defamation
- ☐ Other:

MASS TORT
- ☐ Asbestos
- ☐ Tobacco
- ☐ Toxic Tort - DES
- ☐ Toxic Tort - Implant
- ☐ Toxic Waste
- ☐ Other:

PROFESSIONAL LIABLITY
- ☐ Dental
- ☐ Legal
- ☐ Medical
- ☐ Other Professional:

CONTRACT *(do not include Judgments)*
- ☐ Buyer Plaintiff
- ☐ Debt Collection: Credit Card
- ☐ Debt Collection: Other
- ☐ Employment Dispute: Discrimination
- ☐ Employment Dispute: Other
- ☐ Other:

REAL PROPERTY
- ☐ Ejectment
- ☐ Eminent Domain/Condemnation
- ☐ Ground Rent
- ☐ Landlord/Tenant Dispute
- ☐ Mortgage Foreclosure: Residential
- ☐ Mortgage Foreclosure: Commercial
- ☐ Partition
- ☐ Quiet Title
- ☐ Other:

CIVIL APPEALS
Administrative Agencies
- ☐ Board of Assessment
- ☐ Board of Elections
- ☐ Dept. of Transportation
- ☐ Statutory Appeal: Other
- ☐ Zoning Board
- ☐ Other:

MISCELLANEOUS
- ☐ Common Law/Statutory Arbitration
- ☐ Declaratory Judgment
- ☐ Mandamus
- ☐ Non-Domestic Relations Restraining Order
- ☐ Quo Warranto
- ☐ Replevin
- ☒ Other: Equity - Preliminary and Permanent Injunction

Updated 1/1/2011

IN THE COURT OF COMMON PLEAS OF ALLEGHENY COUNTY, PENNSYLVANIA

ALLEGHENY COUNTY POLICE ASSOCIATION,

Plaintiff,

v.

COUNTY OF ALLEGHENY, PENNSYLVANIA,

Defendant.

CIVIL DIVISION

NO. _____

Code: _____

COMPLAINT IN EQUITY SEEKING PRELIMINARY AND PERMANENT INJUNCTIONS

Filed on behalf of:
Allegheny County Police Association (ACPA), *Plaintiff*

Counsel of Record:

Ronald R. Retsch, Esquire
Pa. I.D. No. 92822

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IN THE COURT OF COMMON PLEAS OF ALLEGHENY COUNTY, PENNSYLVANIA

ALLEGHENY COUNTY POLICE ASSOCIATION, Plaintiff, v. **COUNTY OF ALLEGHENY, PENNSYLVANIA,** Defendant.	**CIVIL DIVISION** **NO.** _____

NOTICE TO DEFEND

You have been sued in court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this complaint and notice are served, by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you. You are warned that if you fail to do so the case may proceed without you and a judgment may be entered against you by the Court without further notice for any money claimed in the complaint or for any claim or relief requested by the Plaintiffs. You may lose money or property or other rights important to you.

YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER AT ONCE. IF YOU DO NOT HAVE A LAWYER, TELEPHONE THE OFFICE SET FORTH BELOW TO FIND OUT WHERE YOU CAN GET LEGAL HELP.

IF YOU CANNOT AFFORD TO HIRE A LAWYER, THIS OFFICE MAY BE ABLE TO PROVIDE YOU WITH INFORMATION ON AGENCIES THAT MAY OFFER LEGAL SERVICES TO ELIGIBLE PERSONS AT A REDUCED FEE OR NO FEE.

Lawyer Referral Service
Allegheny County Bar Association 400 Koppers Building
436 Seventh Avenue
Pittsburgh, PA 15219 Telephone: (412) 261-5555
https://www.getapittsburghlawyer.com/

WELBY, STOLTENBERG,
CIMBALLA & COOK, LLC

By: _____
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Counsel for Plaintiff,
Allegheny County
Police Association

Date: October 14, 2021

IN THE COURT OF COMMON PLEAS OF ALLEGHENY COUNTY, PENNSYLVANIA

ALLEGHENY COUNTY POLICE ASSOCIATION, Plaintiff, v. **COUNTY OF ALLEGHENY, PENNSYLVANIA,** Defendant.	**CIVIL DIVISION** **NO.** _____

COMPLAINT IN EQUITY
SEEKING PRELIMINARY AND PERMANENT INJUNCTIONS

AND NOW comes the Plaintiff, Allegheny County Police Association (ACPA), by and through its counsel, Ronald R. Retsch, Esquire, and Welby, Stoltenberg, Cimballa & Cook, LLC, who files this *Complaint in Equity for Preliminary and Permanent Injunctions* with this Honorable Court pursuant to Pa. R.C.P. No. 1531 and to Pennsylvania law, seeking an Order to preliminarily and thereafter permanently enjoin any vaccine mandate issued or adopted by Allegheny County relating to COVID-19, including but not limited to, the December 1, 2021 COVID-19 vaccine mandate effective on employees of the Executive, noticed by the County on September 29, 2021, and to impose such relief as is necessary, and in support thereof avers as follows:

JURISDICTION

1. This Honorable Court of Common Pleas has original jurisdiction over a complaint in equity seeking a preliminary and a permanent injunction, and the authority to enter injunctive relief, for all other matters whose jurisdiction is not specifically assigned to another court by statute or general rule. 42 Pa. C.S.A. § 761; 42 Pa. C.S.A. § 931;

Citizens Bank of Pennsylvania v. Myers, 872 A.2d 827, 831 n.4 (Pa. Super. 2005)); Buffalo Twp. v. Jones, 571 Pa. 637, 813 A.2d 659 (2002).

PARTIES

2. The preceding and subsequent Paragraphs are incorporated herein as if fully set forth.
3. The Plaintiff, Allegheny County Police Association (ACPA) ("Association"), is a labor organization and the exclusive representative of the bargaining unit of police officers employed by the County of Allegheny pursuant to Act 111 of 1968, 43 P.S. §217.1 *et seq*, and the Pennsylvania Labor Relations Act (hereinafter "PLRA") 43 P.S. §211.1 *et seq*., with a principal place of business at 875 Greentree Road, 10 Parkway Center, Pittsburgh, Allegheny County, PA 15220.
4. The Defendant, County of Allegheny ("County") is a political subdivision of the Commonwealth of Pennsylvania and the public employer of Association's members within the meaning of Act 111 and the PLRA, with a principal place of business at 875 Greentree Road, 10 Parkway Center, Pittsburgh, Allegheny County, PA 15220.
5. The County recognizes the Association as the sole and exclusive bargaining representative of the unit employees with respect to rates of pay, wages, hours of employment and other mandatory subjects of bargaining and terms and conditions of employment pursuant to Act 111 and the PLRA.
6. The Association's members consist of all full-time County Police Officers employed by Allegheny County.
7. The County presently employs an estimated total of Two Hundred Three (203) Association Members.

8. The Association and the County are parties to a Collective Bargaining Agreement (CBA) setting forth wages, hours of work and other terms and conditions of employment and mandatory subjects of bargaining (including matters of discipline). Impasses over new CBAs are submitted to interest arbitration in accordance with PLRA/Act 111, resulting in subsequent interest arbitration awards being incorporated into the CBA. The parties have not yet consolidated the provisions of these subsequent Interest Awards into an updated consolidated CBA; nevertheless, the parties are bound to follow the CBA as amended by mutual settlement agreements and interest arbitration awards issued under the PLRA and Act 111, effective to December 31, 2022.

CASE HISTORY & PARALLEL LITIGATION

9. The preceding Paragraphs are incorporated herein as if fully set forth.

10. The Association avers that its membership includes individuals who are vaccinated against COVID-19 and those who are not. The Association estimates that roughly 156 of its current members are vaccinated against COVID-19 (76.8%), while 47 (23.1%) are not.

11. The Association avers that its membership also includes those who have recovered from COVID-19 infection. For example, 97 members have been given paid time off of work on salary continuation benefits under Act 17 of 2020, 35 Pa. Stat. and Cons. Stat. Ann. § 57A02 (West)[1]. Of those 97 members, 36 tested positive for COVID-19, while 61 of

[1] Session of 2020. No. 2020-17. HB 1869. Act 17 of 2020 provides that employees who are covered under the Enforcement Officer Disability Benefits Act (a/k/a Heart & Lung Act, 53 P.S. § 637 et seq.) who contract or are diagnosed with Coronavirus Disease 2019 (COVID-19), as identified in the Proclamation of Disaster Emergency issued by Governor Wolf on March 6, 2020, published at 50 Pa.B. 1644 (March 21, 2020), or are subject to quarantine resulting from exposure to COVID-19, and by reason thereof are temporarily incapacitated from performing their duties, shall be compensated in accordance with section 1(a) of The Enforcement Officer Disability Benefits law (i.e., provided H&L wage benefits). Receipt of this benefit shall be limited to a maximum of sixty (60) days for each incident.

them were exposed to COVID-19, or considered symptomatic (with 14 of those 61 members ultimately testing negative).

12. Prior to the commencement of this immediate action, on or about August 5, 2021, the County announced a new work rule for Allegheny County employees, which includes all bargaining unit members represented by the Association. **See Complaint Ex. 1.**

13. The rule provides that "Effective Monday, August 9, 2021 , executive branch employees of Allegheny County, including contracted employees, who have not provided proof of vaccination will be required to wear face coverings that cover the person's mouth and nose when indoors at any county facility. The policy also applies when individuals are in any county vehicle when not alone, as well as outdoors in instances when physical distancing is not possible. Additionally, unvaccinated visitors to county facilities will also be asked to mask up when indoors. Signage to that effect will be in place beginning tomorrow with the policy also taking effect on Monday, August 9. Vaccinated employees and visitors may make their own choice regarding masking." The new rule took effect immediately and mandates that County employees who are unvaccinated against COVID-19 shall be required to 1) wear face masks and 2) undergo weekly testing for COVID-19 by way of nasal swab. **See Complaint Ex. 1.**

14. The August 5 work rule also provides that "beginning on August 9, individuals being made conditional job offers with the county will have to be vaccinated as a condition of employment, subject to applicable federal and state laws. The prospective employee will need to be fully vaccinated or have at least one shot of a two-shot series before beginning work. Any employee who does not receive the second shot within 30 days will have their probationary employment terminated. The county is also in the process of finalizing a

testing protocol and expects to begin COVID testing of unvaccinated employees within the next 30-60 days, or sooner as details are finalized. Testing will occur at least once a week and employees, again including contracted employees, will also be required to continue wearing a face covering. Violations of the policy can result in progressive discipline, up to and including termination. The frequency of testing will be determined based on worksite. Additional measures to protect the public will be considered after a review of the data which will begin on October 1. Additional details on the plan are being finalized and will be announced at a later date." See **Complaint Ex. 1.**

15. On September 29, 2021, Allegheny County Executive Rich Fitzgerald announced that the County modified its August 5, 2021 work rule by implementing a COVID-19 vaccine mandate for the Association's bargaining unit members (as they are employees of the County Executive), "subject to such exceptions as required by law". The County cited that the decision was made "in the interest of the health and safety of the county workforce and of the communities we serve, and in light of public health guidance regarding the most effective and necessary defenses against COVID-19…". The County did not indicate that any or all medical or religious exemptions provided by employees would be actually be accepted. The County communicated its mandate to the members via email. See **Complaint Ex. 2**.

16. As a result of this policy change, the Association timely filed Charges of Unfair Labor Practices under the PLRA and Act 111 with the PLRB on September 30, 2021, alleging that the imposition of the COVID-19 vaccination mandate upon the Association's members constitutes a mandatory subject of collective bargaining within the meaning of PLRA and Act 111, specifically Sections 6(1)(a) and (e) because the County did not

bargain with the Association prior to implementing the aforementioned vaccination mandate, but acted unilaterally. See **Complaint Ex. 3.**

17. The Association argues therein that the County is required to rescind the COVID-19 vaccination mandate unless and until it satisfies its collective bargaining obligation pursuant to Act 111 and the PLRA, and requested that the PLRB declare the unilateral imposition of the new vaccination mandate an unfair labor practice within the meaning of Act 111 and Sections 6(1)(a) and (e) of the PLRA, direct the County to rescind the mandate and to cease and desist from engaging in such unlawful actions, and make the bargaining unit members whole for any and all losses sustained due to the unlawful action. All other appropriate relief is requested. All other appropriate relief was requested. See **Complaint Ex. 3.**

18. The PLRB confirmed receipt of the filing of the charge via its email filing system on September 30, 2021. The parties currently await the issuance of a Complaint and Notice of Hearing by the PLRB. See **Complaint Ex. 3.**

COVID-19 & VACCINATIONS

19. The preceding Paragraphs are incorporated herein as if fully set forth.

20. COVID-19 is caused by a coronavirus called SARS-CoV-2. The CDC advises that "this type of coronavirus has not been seen before (a "novel" virus"). A person can contract COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. Those with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus, and common symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new

loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; or diarrhea". See **Complaint Ex. 4, p 1.**

21. Pursuant to the Johns Hopkins University Coronovirus Resource Center, the following is a summary of the COVID-19 cases and mortality statistics for the United States, Pennsylvania and Allegheny County, as of September 30, 2021, showing that Allegheny County case fatality rate is consistent with the overall national average[2]:

Cases and mortality – Unit States as of September 30, 2021[3]

Country	Total Country Population	Confirmed Cases	Deaths	Case Fatality	Deaths/100,000 population
United States	328,232,305	43,349,211	695,114	1.6%	211.77

Cases and mortality – Pennsylvania as of September 30, 2021[4]

State	Total State Population	Confirmed Cases	Deaths	Case Fatality	Deaths/100,000 population
Pennsylvania	12,791,887	1,425,048	29,323	2.06%	228

Cases and mortality - Allegheny County as of September 30, 2021[5]

County	Total County Population	Confirmed Cases	Deaths	Case Fatality	Deaths/100,000 population
Allegheny	1,221,744	120,573	2,160	1.79%	216

[2] See "Mortality Analyses", Johns Hopkins University & Medicine at https://coronavirus.jhu.edu/data/mortality
[3] Source: https://coronavirus.jhu.edu/region/united-states 9.30.2021
[4] Source: https://coronavirus.jhu.edu/region/us/pennsylvania 9.30.2021; see also "Death rates from coronavirus (COVID-19) in the United States as of October 11, 2021, by state (per 100,000 people)", Statista at https://www.statista.com/statistics/1109011/coronavirus-covid19-death-rates-us-by-state/ 9.30.2021
[5] Source: https://coronavirus.jhu.edu/us-map ; https://bao.arcgis.com/covid-19/jhu/county/42003.html 9.30.2021

22. According to the CDC, COVID-19 overall has a 99.74% survival rate. Among young people, that number is even higher. For people aged 18 to 29, the survival rate is 99.97%.[6]

23. Since the emergence of the virus, and because of the federal government's "Operation Warp Speed," three separate COVID-19 vaccines have been developed and approved more swiftly than any other vaccines in our nation's history. See **Complaint Ex. 4.**

24. According to the CDC, there are 186.1 million fully COVID-19 vaccinated persons in the US, or 56% of the US population, as of October 5, 2021[7]. As of September 30, 2021, there are a total of 43,349,211 confirmed cases of COVID-19 infection since the start of the pandemic.[8] Accordingly, the same number of persons have achieved natural immunity by way of recovery from COVID-19[9] without (before) the administration of vaccinations.

25. The County mandate requires "current County employees (including Association members) must show proof of their second dose of a two-dose COVID-19 vaccine, or proof of a one-dose vaccine on or before December 1, 2021". Specifically, this means proof that the member received the 2nd dose of a two-dose vaccine (Pfizer and/or Moderna) or proof of having received a single dose of the Johnson & Johnson one-dose vaccine. Members who are vaccinated are required to show proof thereof, and those who are not vaccinated are required to become vaccinated and to show proof of same (though

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[6] See "Provisional COVID-19 Deaths by Sex and Age ", CDC at https://data.cdc.gov/NCHS/Provisional-COVID-19-Death-Counts-by-Sex-Age-and-S/9bhg-hcku/data

[7] See "COVID-19 Vaccinations in the United States", CDC at https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total.

[8] Source: https://coronavirus.jhu.edu/region/united-states 9.30.2021

[9] See Han Y, Liu P, Zhou J, et al. Effective virus-neutralizing activities in antisera from the first wave of survivors of severe COVID-19. Journal of Clinical Investigation Insight, 2021;6(4):3146267. https://insight.jci.org/articles/view/146267. See also Gaebler C, Wang Z, Lorenzi JCC, et al. Evolution of antibody immunity to SARS-CoV-2. Nature 591, 639–644 (2021). https://www.nature.com/articles/s41586-021-03207-w.

it doesn't specify what proof would be sufficient). The County communicated its mandate to the Association members via email, which includes a citation to the website of the United States Centers for Disease Control (CDC). See **Complaint Ex. 2**.

26. The County's mandate also advised that "employees who have submitted proof of vaccination will be entitled to up to eighty (80) hours of paid leave for reasons related to COVID-19: 1) if an employee tests positive for COVID-19; 2) if an employee is subject to a Federal, State, or local quarantine or isolation order related to COVID-19; or 3) if an employee has been advised by a health care provider to self-quarantine related to COVID-19 (with appropriate documentation provided by the employee)". See **Complaint Ex. 2**.

27. The County's mandate announced that employees failing to provide proof of vaccination by December 1, 2021 "will be subject to termination of employment". The County does not define what "full vaccination" means in this context. See **Complaint Ex. 2**.

28. The CDC states that "fully vaccinated" for medical purposes is *not* when the injection is received, *but when the effect of the injection is produced:* "People are *considered fully vaccinated 2 weeks after their second dose* of the Pfizer-BioNTech or Moderna COVID-19 vaccines, or *2 weeks after the single-dose* Johnson & Johnson's Janssen COVID-19 vaccine[10]" The County's mandate does not provide guidance on that point in terms of how that affects compliance with its mandate.

29. There are three (3) COVID-19 vaccines at issue, which require different dosage schedules. See **Complaint Ex. 4.**

[10] "Key Things to Know About COVID-19 Vaccines", CDC at https://www.cdc.gov/coronavirus/2019-ncov/vaccines/keythingstoknow.html#:~:text=COVID%2D19%20vaccines%20teach,19%20just%20after%20vaccination

30. Conventional vaccinations inject a weakened or inactivated germ or virus (an antigen[11]) into the body to trigger an immune response according to their respective dosage schedules[12]. For example, Pennsylvania law addresses vaccinations in regard to children. 28 Pa. Code § 23.81, Subchapter C. *Immunization*, provides for "mandatory" vaccinations of children against certain diseases so as to attend school (subject to medical and religious exemptions). To that end, 28 Pa. Code § 23.82, *Definitions*, defines "Immunization" as "[t]he requisite number of *dosages of* the specific *antigens* at the recommended time intervals under this subchapter." § 23.82 defines "Full immunization" as "[t]he completion of the requisite number of *dosages of* the specific *antigens* at recommended time and age intervals as set forth in § 23.83 (relating to immunization requirements) (emphasis added).

31. 28 Pa. Code § 23.84(a). *Exemption from immunization*, provides for medical exemptions from vaccinations for children, holding that, "[c]hildren need not be immunized if a physician or the physician's designee provides a written statement that immunization may be detrimental to the health of the child. When the physician determines that immunization is no longer detrimental to the health of the child, the child shall be immunized according to this subchapter".

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[11] An "antigen" is any substance that causes the body to make an immune response *against that substance*. Antigens include toxins, chemicals, bacteria, viruses, or other substances that come from outside the body. See the National Cancer Institute definition of "antigen" at https://www.cancer.gov/publications/dictionaries/cancer-terms/def/antigen. "Antigens" are molecular structures on the surface of viruses that are recognized by the immune system and are capable of triggering an immune response (antibody production). On influenza viruses, the major antigens are found on the virus' surface proteins. See "Antigenic Characterization", CDC at https://www.cdc.gov/flu/about/professionals/antigenic.htm.

[12] See "Understanding How Vaccines Work", CDC at https://www.cdc.gov/vaccines/hcp/conversations/understanding-vacc-work.html. These methods include Live, attenuated vaccines (such as the Smallpox vaccine, the MMR vaccine and some influenza vaccines); Inactivated vaccines (such as the polio vaccine and some influenza vaccines); Toxoid vaccines (such as the DTaP vaccine); Subunit vaccines (such as the DTaP vaccine); and Conjugate vaccines (such as the Haemophilus influenzae type B (Hib) vaccine). See also "Smallpox", FDA at https://www.fda.gov/vaccines-blood-biologics/vaccines/smallpox.

32. Further, 28 Pa. Code § 23.84(b). *Exemption from immunization*, provides for religious exemptions from vaccination for children, holding that, "[c]hildren need not be immunized if the parent, guardian or emancipated child objects in writing to the immunization on religious grounds or on the basis of a strong moral or ethical conviction similar to a religious belief."[13]

33. However, the processes that the three COVID-19 vaccines at issue utilize to trigger an immune response are different in that they *do not involve the injection of an antigen.*

34. According to the CDC, the three vaccines differ in their prescribed dosage schedules in order to achieve "full vaccination".

35. The first, **J&J-BioNTech (Janssen)**, is a "Viral vector" vaccine, and requires one (1) injection[14]. See **Complaint Ex. 4., p. 1**. Viral vector vaccines use a modified version of a different virus (the vector) to deliver important instructions to body cells. Viral vector-based vaccines differ from most conventional vaccines (and those defined in Pennsylvania law) *in that they don't actually contain and inject antigens*, but rather use the *body's own cells to produce the antigens*[15].

36. The viral vector that forms the backbone of the J&J vaccine is grown in a continuous ("immortalized") human embryonic cell line (PER.C6) derived from the abortion of a healthy 18-week-old fetus, leading some Catholic leaders to describe the vaccine as

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[13] All vaccine providers, public or private, are required by the National Vaccine Childhood Injury Act (NCVIA – 42 U.S.C. § 300aa-26) to give the appropriate Vaccine Information Statement (VIS) to the patient (or parent or legal representative) prior to every dose of *specific* vaccines defined by the Act. However, there is no COVID-19 Vaccine Information Statement as they all remain subject to Emergency Use Authorizations.

[14] See "Johnson & Johnson's Janssen COVID-19 Vaccine Overview and Safety", CDC at https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/janssen.html

[15] See "What are viral vector-based vaccines and how could they be used against COVID-19?", GAVI, at https://www.gavi.org/vaccineswork/what-are-viral-vector-based-vaccines-and-how-could-they-be-used-against-covid-19#:~:text=Viral%20vector%2Dbased%20vaccines,cells%20to%20produce%20them.

"morally compromised.[16]" FDA officials have acknowledged for over two decades that such cell lines are a "major safety concern.[17]"

37. A single injection of the J&J-BioNTech (Janssen) vaccine must be received on or before the County's deadline of December 1, 2021. However, taking a two (2) week "CDC effective period" into account, then the last required injection must be received by Wednesday, November 17, 2021 to be "fully vaxed" by December 1, per the CDC guideline. The County mandate provides no guidance on how this may affect compliance with its mandate, and thus, how it will affect potential officer discipline.

38. The second vaccine, **Moderna,** is an "mRNA" vaccine which requires two (2) injections, administered **28 days** apart[18]. See **Complaint Ex. 4., p. 8**.

39. If the County's deadline is December 1, 2021, and a person receives the second injection of Moderna on December 1, 2021, then 28 days before that date is **Wednesday, November 3, 2021**, making that the latest date to obtain the first Moderna injection. However, taking a 2 week "CDC effective period" into account, then the second Moderna injection must be received by **Wednesday, November 17, 2021**, and the first must be received 28 days earlier on **Wednesday, October 20, 2021.** The County mandate provides no guidance on how this may affect compliance with its mandate, and thus, how it will affect potential officer discipline.

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[16] See "New Orleans archdiocese urges Catholics to avoid new Johnson & Johnson vaccine", Religion News Service, https://religionnews.com/2021/03/01/new-orleans-archdiocese-urges-catholics-to-avoid-new-johnson-johnson-vaccine/

[17] See "Investigating Viruses in Cells Used to Make Vaccines; and Evaluating the Potential Threat Posed by Transmission of Viruses to Humans", FDA at https://www.fda.gov/vaccines-blood-biologics/biologics-research-projects/investigating-viruses-cells-used-make-vaccines-and-evaluating-potential-threat-posed-transmission

[18] See "Moderna COVID-19 Vaccine Overview and Safety" CDC at https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/Moderna.html

40. The third vaccine, **Pfizer-BioNtech** (Brand name **Comirnaty**), is also an mRNA vaccine which requires two (2) injections, administered **21 days** apart[19]. See **Complaint Ex. 4., p. 14**.

41. If the County's deadline is December 1, 2021, and a person receives the second Pfizer injection on December 1, 2021, then 21 days before that date is **Wednesday, November 10, 2021**, making that the latest date to obtain the first Pfizer injection. However, taking a 2 week "CDC effective period" into account, then the second Pfizer injection must be received by **Wednesday, November 17, 2021**, and the first must be received 21 days earlier on **Wednesday, October 27, 2021**. The County mandate provides no guidance on how this may affect compliance with its mandate, and thus, how it will affect potential officer discipline.

42. Further, per the CDC with regard to the Pfizer vaccination, "[m]oderately to severely immunocompromised people should get an additional shot (3rd dose) at least 28 days after their 2nd shot. Other groups of people are recommended to get a booster shot at least 6 months after getting their 2nd shot."[20] The County mandate provides no guidance on how this may affect compliance with its mandate, and thus, how it will affect potential officer discipline.

43. The Moderna and Pfizer vaccines are both Messenger RNA vaccines ("mRNA vaccines"). They are some of the first COVID-19 vaccines authorized for use in the

[19] See "Pfizer-BioNTech COVID-19 Vaccine Overview and Safety (also known as COMIRNATY)" CDC at https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/Pfizer-BioNTech.html

[20] See "Understanding mRNA COVID-19 Vaccines" CDC at https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mRNA.html?s_cid=11344:mrna%20vaccine:sem.ga:p:RG:GM:gen:PTN:FY21

United States[21] and are the first messenger RNA vaccines to be produced and tested in large-scale Phase III human trials[22].

44. mRNA vaccines are a new type of vaccine utilized to protect against infectious diseases. To trigger an immune response, many vaccines inject a weakened or inactivated germ (an antigen) into the body. mRNA vaccines, however, instead instruct cells how to make a protein—or even just a piece of a protein—that triggers an immune response inside the body. That immune response, which produces antibodies, is what the vaccines' producers say protect the patient from getting infected if the real virus enters the body. COVID-19 mRNA vaccines give instructions for the body's cells to manufacture a "spike protein", which is found on the surface of the virus that causes COVID-19. This is a different delivery method than that defined for a conventional vaccine under Pennsylvania law.
45. The FDA issued an Emergency Use Authorization (EUA) for the Pfizer-BioNTech Vaccine on December 11, 2020.
46. The FDA issued an EUA for the Moderna Vaccine on December 18, 2020.
47. FDA issued its most recent EUA for the J&J Janssen Vaccine on February 27, 2021.
48. The Pfizer Comirnaty Vaccine received "full FDA approval" on August 23, 2021.

EUA VACCINES & FACT SHEETS

49. The preceding Paragraphs are incorporated herein as if fully set forth.
50. Per the CDC, vaccination, like any medical treatment, carries the potential for side effects, some of which can be severe[23]. Even fully FDA-approved treatments (including

[21] See "Understanding mRNA COVID-19 Vaccines" CDC at https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mRNA.html?s_cid=11344:mrna%20vaccine:sem.ga:p:RG:GM:gen:PTN:FY21
[22] See "What's Different About Messenger RNA (mRNA) Vaccines for COVID-19?", Memorial Sloan Kettering Cancer Center at https://www.mskcc.org/coronavirus/what-s-different-about-messenger-rna-vaccines-covid-19
[23] See https://www.cdc.gov/vaccines/vac-gen/side-effects.htm "Vaccines are continually monitored for safety, and like any medication, vaccines can cause side effects."

vaccinations and therapeutics[24]) may nevertheless result in serious injury and death, causing revocation of said approval and/or removal from use.[25]

51. The FDA and CDC offer only "recommendations" and "guidance" on the use of medical treatments.[26]

52. The CDC advises that "a COVID-19 vaccine is currently available through Emergency Use Authorization (EUA) by the Food and Drug Administration (FDA). EUA ***Fact Sheets for Recipients*** should be provided to patients at the time of vaccination"[27]. The *Recipient* Fact Sheets for all three COVID-19 vaccinations are attached hereto as **Complaint Ex. 4.** The EUA *Health Care Provider* Fact Sheets for all three COVID-19 vaccines are attached at **Complaint Ex. 5.** The Fact Sheets provide explanations of the EUA status of the vaccines; summaries of potential side effects; warnings that other side effects may be possible; and advice on seeking medical care if side effects occur or persist, including reporting such side effects to the Federal medical agencies.

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[24] NPR.com, "*One-Third of New Drugs Had Safety Problems After FDA Approval*", May 9, 2017, "Researchers at the Yale School of Medicine found that nearly a third of those approved from 2001 through 2010 had major safety issues years after the medications were made widely available to patients. Seventy-one (71) of the 222 drugs approved in the first decade of the millennium were withdrawn, required a "black box" warning on side effects or warranted a safety announcement about new risks See https://www.npr.org/sections/health-shots/2017/05/09/527575055/one-third-of-new-drugs-had-safety-problems-after-fda-approval?utm_campaign=storyshare&utm_source=twitter.com&utm_medium=social

[25] "Patients might think the US Food and Drug Administration's stamp of approval means that a product is the last word on safety, but about a third of the drugs the FDA approved between 2001 and 2010 were involved in some kind of safety event after reaching the market, according to a study published Tuesday in the Journal of the American Medical Association. The authors found that in that time, 222 novel therapeutics were approved, and there were 123 postmarket safety events involving 71 products that required FDA action. Manufacturers needed to add 61 boxed warnings, also commonly called a black box warning, to call attention to serious or life-threatening risks. In 59 cases, some kind of communication had to warn users about a product's safety. Three therapeutics were withdrawn from the market". https://www.cnn.com/2017/05/09/health/fda-approval-drug-events-study/index.html

[26] See "Requirements & Laws", CDC at https://www.cdc.gov/vaccines/imz-managers/laws/index.html; see also "Workplaces and Businesses", CDC at https://www.cdc.gov/coronavirus/2019-ncov/community/workplaces-businesses/index.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fvaccines%2Ftoolkits%2Fessential-workers.html

[27] See "Current VISs", CDC at https://www.cdc.gov/vaccines/hcp/vis/current-vis.html; see also "COVID-19 Vaccine Emergency Use Authorization (EUA) Fact Sheets for Recipients and Caregivers", CDC at https://www.cdc.gov/vaccines/covid-19/eua/index.html.

53. The Fact Sheets describe the Emergency Use Authorization of the vaccines, stating that, "[t]he United States FDA has made the [each COVID-19 Vaccine] available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic. [Each COVID-19 Vaccine] has not undergone the same type of review as an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used during the COVID-19 pandemic. The EUA for [each COVID-19 Vaccine] is in effect for the duration of the COVID-19 declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used)". See **Complaint Ex. 4, p. 7, 13, and 20.**

54. The Recipient Fact Sheet for the **J&J-Janssen** Vaccine at **Complaint Ex. 4, p. 1 to 7** provides, in relevant part, the following advisory information:

    a. The United States FDA has made the Janssen COVID-19 Vaccine **available under an emergency access mechanism called an EUA.** The EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

    b. The FDA has authorized the emergency use of the Janssen COVID-19 Vaccine to prevent COVID-19 in individuals 18 years of age and older under an Emergency Use Authorization (EUA).

c. The Janssen COVID-19 Vaccine **is an unapproved vaccine that may prevent COVID-19**. In an ongoing clinical trial, 21,895 individuals 18 years of age and older have received the Janssen COVID-19 Vaccine.

d. In an ongoing clinical trial, the Janssen COVID-19 Vaccine has been shown to prevent COVID-19 following a single dose.

e. The **duration of protection** against COVID-19 **is currently unknown**.

f. The Janssen COVID-19 Vaccine **may prevent you from getting COVID-19.**

g. The Janssen COVID-19 Vaccine **may not protect everyone.**

h. When you receive the Janssen COVID-19 Vaccine, you will get a vaccination card to document the name of the vaccine and date of when you received the vaccine.

i. **It is your choice to receive or not receive the Janssen COVID-19 Vaccine**. Should you **decide not to receive it, it will not change your standard medical care.**

j. The Janssen COVID-19 Vaccine **does not contain SARS-CoV-2** and cannot give you COVID-19.

k. There is **no information on the use of the Janssen COVID-19 Vaccine with other vaccines.**

l. **The Janssen COVID-19 Vaccine has not undergone the same type of review as an FDA-approved or cleared product**. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used during the COVID-19 pandemic.

m. The EUA for the Janssen COVID-19 Vaccine is in effect for the duration of the COVID-19 declaration justifying emergency use of these products**, unless terminated or revoked (after which the products may no longer be used).**

n. **Tell the vaccination provider about all of your medical conditions, including if you**:

i. have any allergies; have a fever; have a bleeding disorder or are on a blood thinner; are immunocompromised or are on a medicine that affects your immune system; are pregnant or plan to become pregnant; are breastfeeding; have received another COVID-19 vaccine; have ever fainted in association with an injection.

o. **You should not get the Janssen COVID-19 Vaccine if you had a severe allergic reaction to any ingredient of this vaccine.** The Janssen COVID-19 Vaccine includes the following ingredients: recombinant, replication-incompetent adenovirus type 26 expressing the SARS-CoV-2 spike protein, citric acid monohydrate, trisodium citrate dihydrate, ethanol, 2-hydroxypropyl-β-cyclodextrin (HBCD), polysorbate-80, sodium chloride.

p. **Side effects that have been reported with the Janssen COVID-19 Vaccine include:**

i. Injection site reactions: pain, redness of the skin and swelling.

ii. General side effects: headache, feeling very tired, muscle aches, nausea, and fever.

iii. Swollen lymph nodes.

iv. Unusual feeling in the skin (such as tingling or a crawling feeling) (paresthesia), decreased feeling or sensitivity, especially in the skin (hypoesthesia).

v. Persistent ringing in the ears (tinnitus).

vi. Diarrhea, vomiting.

vii. **Severe Allergic Reactions** - There is a remote chance that the Janssen COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Janssen COVID-19 Vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include: Difficulty breathing; Swelling of your face and throat; A fast heartbeat; A bad rash all over your body; Dizziness and weakness.

viii. **Blood Clots with Low Levels of Platelets** - Blood clots involving blood vessels in the brain, lungs, abdomen, and legs along with low levels of platelets (blood cells that help your body stop bleeding), have occurred in

some people who have received the Janssen COVID-19 Vaccine. In people who developed these blood clots and low levels of platelets, symptoms began approximately one to two weeks after vaccination. Reporting of these blood clots and low levels of platelets has been highest in females ages 18 through 49 years. The chance of having this occur is remote. You should seek medical attention right away if you have any of the following symptoms after receiving Janssen COVID-19 Vaccine: Shortness of breath, Chest pain, Leg swelling, Persistent abdominal pain, Severe or persistent headaches or blurred vision, Easy bruising or tiny blood spots under the skin beyond the site of the injection.

ix. **These may not be all the possible side effects of the Janssen COVID-19 Vaccine. Serious and unexpected effects may occur. The Janssen COVID-19 Vaccine is still being studied in clinical trials.**

x. **Guillain Barré Syndrome** - Guillain Barré syndrome (a neurological disorder in which the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis) has occurred in some people who have received the Janssen COVID-19 Vaccine. In most of these people, symptoms began within 42 days following receipt of the Janssen COVID-19 Vaccine. The chance of having this occur is very low. You should seek medical attention right away if you develop any of the following symptoms after receiving the Janssen COVID-19 Vaccine: Weakness or tingling sensations, especially in the legs or arms, that's worsening and spreading to other parts of the body; Difficulty walking; Difficulty with facial movements, including speaking, chewing, or swallowing; Double vision or inability to move eyes; Difficulty with bladder control or bowel function.

xi. **If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital. Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away. Report vaccine side effects to FDA/CDC Vaccine Adverse Event Reporting System (VAERS).**

xii. **The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses for certain people who have been seriously injured by certain medicines or vaccines, including this vaccine**. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine.

Emphasis added.

55. The Recipient Fact Sheet for the **Moderna** Vaccine at **Complaint Ex. 4, p. 8 to 13** provides, in relevant part, the following advisory information:

a. The FDA has **authorized the emergency use of the Moderna COVID-19 Vaccine to prevent COVID-19** in individuals 18 years of age and older under an Emergency Use Authorization (EUA).

b. FDA has authorized the **emergency use of the Moderna COVID-19 Vaccine** in individuals 18 years of age and older.

c. **The Moderna COVID-19 Vaccine is an unapproved vaccine**. In clinical trials, approximately 15,400 individuals 18 years of age and older have received at least 1 dose of the Moderna COVID-19 Vaccine. In an ongoing clinical trial, the Moderna COVID-19 Vaccine has been shown to prevent COVID-19 following 2 doses given 1 month apart.

d. The **duration of protection** against COVID-19 is **currently unknown.**

e. **If you are immunocompromised, you may receive a third dose of the Moderna COVID-19 Vaccine**. The third dose may still not provide full immunity to COVID-19 in people who are immunocompromised, and you should continue to maintain physical precautions to help prevent COVID-19. In addition, your close contacts should be vaccinated as appropriate.

f. The Moderna COVID-19 Vaccine is a vaccine **and may prevent you from getting COVID-19.**

g. The Moderna COVID-19 Vaccine **is an unapproved vaccine that may prevent COVID-19.**

h. The Moderna COVID-19 Vaccine **may not protect everyone**.

i. The Moderna COVID-19 Vaccine **does not contain SARS-CoV-2** and cannot give you COVID-19.

j. There is **no information on the use of the Moderna COVID-19 Vaccine with other vaccines**.

k. It is your choice to receive or not receive the Moderna COVID-19 Vaccine. Should you decide not to receive it, it will not change your standard medical care.

l. The Moderna COVID-19 Vaccine will be given to you as an injection into the muscle. The Moderna COVID-19 Vaccine vaccination series is 2 doses given 1 month apart. If you receive one dose of the Moderna COVID-19 Vaccine, you should receive a second dose of the same vaccine 1 month later to complete the vaccination series. If you are immunocompromised, you may receive a third dose of the Moderna COVID-19 Vaccine at least 1 month after the second dose.

m. When you receive your first dose, you will get a vaccination card to show you when to return for your second dose of the Moderna COVID-19 Vaccine. Remember to bring your card when you return.

n. Tell your vaccination provider about all of your medical conditions, including if you:

i. have any allergies;
ii. have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
iii. have a fever
iv. have a bleeding disorder or are on a blood thinner
v. are immunocompromised or are on a medicine that affects your immune system
vi. are pregnant or plan to become pregnant
vii. are breastfeeding
viii. have received another COVID-19 vaccine
ix. have ever fainted in association with an injection

o. You should not get the Moderna COVID-19 Vaccine if you:

i. had a severe allergic reaction after a previous dose of this vaccine.
ii. **had a severe allergic reaction to any ingredient of this vaccine.** The Moderna COVID-19 Vaccine contains the following ingredients: messenger ribonucleic acid (mRNA), lipids (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate trihydrate, and sucrose.

p. **There is a remote chance that the Moderna COVID-19 Vaccine could cause a severe allergic reaction**. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Moderna COVID-19 Vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include: Difficulty breathing; Swelling of your face and throat; A fast heartbeat; A bad rash all over your body; Dizziness and weakness

q. **Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the Moderna COVID-19 Vaccine.** In most of these people, symptoms began within a few days following receipt of the second dose of the Moderna COVID-19 Vaccine. The chance of having this occur is very low. You should seek medical attention right away if you have any of the following symptoms after receiving the Moderna COVID-19 Vaccine: Chest pain; Shortness of breath; Feelings of having a fast-beating; fluttering; or pounding heart

r. **Side effects that have been reported in a clinical trial with the Moderna COVID-19 Vaccine include:** Injection site reactions: pain, tenderness and swelling of the lymph nodes in the same arm of the injection, swelling (hardness), and redness; General side effects: fatigue, headache, muscle pain, joint pain, chills, nausea and vomiting, and fever

s. **Side effects that have been reported during post-authorization** use of the Moderna COVID-19 Vaccine include:

   i. **Severe allergic reactions**
   ii. **Myocarditis (inflammation of the heart muscle)**
   iii. **Pericarditis (inflammation of the lining outside the heart)**

t. **These may not be all the possible side effects of the Moderna COVID-19 Vaccine. Serious and unexpected side effects may occur. The Moderna COVID-19 Vaccine is still being studied in clinical trials.**

u. If you **experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital. Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away. Report vaccine side effects to FDA/CDC Vaccine Adverse Event Reporting System (VAERS)**.

v. **The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine.** Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine.

Emphasis added.

56. The Recipient Fact Sheet for the **Pfizer-BioNTech** Vaccine (and the Comirnaty Brand Name version) at **Complaint Ex. 4, p. 14 to 21** provides in relevant part:

a. You are being offered either COMIRNATY (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Vaccine Information Fact Sheet for Recipients and Caregivers comprises the Fact Sheet for the authorized Pfizer-BioNTech COVID-19 Vaccine and also includes information about the FDA-licensed vaccine, COMIRNATY (COVID-19 Vaccine, mRNA). The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the FDA-authorized Pfizer-BioNTech COVID-19 Vaccine under Emergency Use Authorization (EUA) have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series. The licensed vaccine has the same formulation as the EUA-authorized vaccine and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns. **The products are legally distinct with certain differences that do not impact safety or effectiveness.**

b. COMIRNATY (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine made by Pfizer for BioNTech. It is approved as a 2-dose series for prevention of COVID-19 in individuals 16 years of age and older. It is also authorized under EUA to provide:

    i. a two-dose primary series in individuals 12 through 15 years;
    ii. a third primary series dose in individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise; and
    iii. a single booster dose in individuals:
        1. 65 years of age and older;
        2. 18 through 64 years of age at high risk of severe COVID-19;
        3. 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19.

    iv. The Pfizer-BioNTech COVID-19 Vaccine has received EUA from FDA to provide:

        1. a two-dose primary series in individuals 12 years of age and older;
        2. a third primary series dose for individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise; and
        3. a single booster dose in individuals:
            a. 65 years of age and older;
            b. 18 through 64 years of age at high risk of severe COVID-19;
            c. 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19.

v. The vaccine will be given to you as an injection into the muscle.

1. Primary Series: The vaccine is administered as a 2-dose series, 3 weeks apart. A third dose may be administered at least 4 weeks after the second dose to individuals who are determined to have certain kinds of immunocompromise.
2. Booster Dose: A single booster dose of the vaccine may be administered to individuals:
    a. 65 years of age and older;
    b. 18 through 64 years of age at high risk of severe COVID-19;
    c. 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19.

c. In clinical trials, approximately 23,000 individuals 12 years of age and older have received at least 1 dose of the vaccine. Data from these clinical trials supported the Emergency Use Authorization of the Pfizer-BioNTech COVID-19 Vaccine and the approval of COMIRNATY (COVID-19 Vaccine, mRNA). Millions of individuals have received the vaccine under EUA since December 11, 2020.

d. **Data have not yet been submitted to FDA on administration of COMIRNATY (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech COVID-19 Vaccine at the same time with other vaccines**. If you are considering receiving COMIRNATY (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech COVID-19 Vaccine with other vaccines, discuss your options with your healthcare provider.

e. The **vaccine does not contain SARS-CoV-2** and cannot give you COVID-19.

f. Under the EUA, it is your choice to receive or not receive the vaccine. Should you decide not to receive it, it will not change your standard medical care.

g. **If you are immunocompromised, you may receive a third dose of the vaccine.** The third dose may still not provide full immunity to COVID-19 in people who are immunocompromised, and you should continue to maintain physical precautions to help prevent COVID-19. In addition, your close contacts should be vaccinated as appropriate.

h. Tell the vaccination provider about all of your medical conditions, including if you:

vi. have any allergies;

vii. have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart) ;
viii. have a fever;
ix. have a bleeding disorder or are on a blood thinner;
x. are immunocompromised or are on a medicine that affects your immune system;
xi. are pregnant or plan to become pregnant;
xii. are breastfeeding;
xiii. have received another COVID-19 vaccine;
xiv. have ever fainted in association with an injection;

i. The vaccine has been shown to prevent COVID-19.

j. The **duration of protection against COVID-19 is currently unknown.**

k. The **vaccine may not protect everyone.**

l. You should not get the vaccine if you:

xv. had a severe allergic reaction after a previous dose of this vaccine;
xvi. **had a severe allergic reaction to any ingredient of this vaccine**. The vaccine includes the following ingredients: mRNA, lipids ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2 [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3-phosphocholine, and cholesterol), potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose.

m. **There is a remote chance that the vaccine could cause a severe allergic reaction.** A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

xvii. Difficulty breathing; Swelling of your face and throat; A fast heartbeat; A bad rash all over your body; Dizziness and weakness

n. **Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the vaccine**. In most of these people, symptoms began within a few days following receipt of the second dose of vaccine. The chance of having this occur is very low. You should seek medical attention right away if you have any of the following symptoms after receiving the vaccine: Chest pain; Shortness of breath; Feelings of having a fast-beating, fluttering, or pounding heart.

o. **Side effects that have been reported with the vaccine include**:

xviii. severe allergic reactions; non-severe allergic reactions such as rash, itching, hives, or swelling of the face; myocarditis (inflammation of the heart muscle) ; pericarditis (inflammation of the lining outside the heart); injection site pain; tiredness; headache; muscle pain; chills; joint pain; fever; injection site swelling; injection site redness; nausea; feeling unwell; swollen lymph nodes (lymphadenopathy); decreased appetite; diarrhea; vomiting; arm pain; and fainting in association with injection of the vaccine

p. **These may not be all the possible side effects of the vaccine. Serious and unexpected side effects may occur. The possible side effects of the vaccine are still being studied in clinical trials.**

q. **If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital. Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away. Report vaccine side effects to FDA/CDC Vaccine Adverse Event Reporting System (VAERS).**

r. **The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine.** Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine.

Emphasis added.

57. Under the Federal Food, Drug, and Cosmetic Act, 21 U.S. Code § 301, 21 U.S.C.A. § 360bbb-3, the FDA may issue an EUA for an unapproved drug, biological product, or device; or for an unapproved use of a drug, biological product or device following a Declaration by the Secretary of Health and Human Services that the circumstances justify such authorization, such as a determination by the Health and Human Services Secretary that there is a public health emergency or a significant potential for a public health emergency that affects, or has significant potential to affect, national security or the health and security of U.S. citizens living abroad and involves a biological, chemical,

radiological, or nuclear agent(s) or disease or condition that may be attributable to such agent(s).

58. Pursuant to 21 U.S.C.A. § 360bbb-3(c), *Criteria for issuance of authorization*, the FDA may then issue an EUA for a product [like a vaccine] as follows:

> The Secretary may issue an authorization under this section with respect to the emergency use of a product only if, after consultation with the Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the applicable circumstances described in subsection (b)(1)), the Secretary concludes--
>
> > (1) that an agent referred to in a declaration under subsection (b) can cause a serious or life-threatening disease or condition;
> >
> > (2) that, based on the totality of scientific evidence available to the Secretary, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that--
> >
> > > (A) the product may be effective in diagnosing, treating, or preventing--
> > >
> > > > (i) such disease or condition; or
> > > >
> > > > (ii) a serious or life-threatening disease or condition caused by a product authorized under this section, approved or cleared under this chapter, or licensed under section 351 of the Public Health Service Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and
> > >
> > > **(B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under subsection (b)(1)(D), if applicable;**
> >
> > (3) **that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition;**

> (4) in the case of a determination described in subsection (b)(1)(B)(ii), that the request for emergency use is made by the Secretary of Defense; and
>
> (5) that such other criteria as the Secretary may by regulation prescribe are satisfied.
>
> (Emphasis added).

59. The FDA will, in issuing the EUA, impose conditions on the emergency use that is authorized[28]. See **Complaint Ex. 4.**

60. As detailed herein above and in **Complaint Ex. 4 and 5**, two of the SARS-CoV-2 vaccines currently have only Emergency Use Authorization (with Pfizer receiving a biologics license application from the FDA for its vaccine Comirnaty for ages 16 and older, but remaining subject to EUA approval for ages 12 to 15, as of February 27, 2021.[29]

61. The CDC admits that "it is not known if Comirnaty protects against asymptomatic SARS-CoV-2 infection.... Most vaccines that protect from viral illnesses also reduce transmission of the virus that causes the disease by those who are vaccinated. While it is hoped this will be the case, the scientific community does not yet know if Comirnaty will reduce such transmission".[30]

62. The CDC confirms that "after issuance of the EUA, clinical trial participants were *unblinded* in a phased manner over a period of months to offer the authorized Pfizer-BioNTech COVID-19 Vaccine to placebo participants (meaning, the control group of the

[28] See also "Emergency Use Authorization", US Dept. of Health & Human Services, at https://www.phe.gov/Preparedness/planning/authority/Pages/eua.aspx.
[29] See "Janssen COVID-19 Vaccine", FDA at https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine
[30] See "Q&A for Comirnaty (COVID-19 Vaccine mRNA)", FDA at https://www.fda.gov/vaccines-blood-biologics/qa-comirnaty-covid-19-vaccine-mrna

clinical trial was given the vaccine as well). These participants were followed for safety outcomes. Overall, in blinded and unblinded follow-up, approximately 12,000 Pfizer-BioNTech COVID-19 Vaccine recipients have been followed for at least 6 months"[31].

63. The CDC confirms that "there are no data available on the interchangeability of Comirnaty with either Moderna COVID-19 Vaccine or Janssen COVID-19 Vaccine"[32]. See **Complaint Ex. 4.**

64. All existing Pfizer vials (in the hundreds of millions), remain under the federal Emergency Use Authorization (EUA) (meaning people have the "option to accept or refuse");

65. BioNTech received FDA approval for people ages 16 and above under the name Comirnaty, but there are no Comirnaty doses available in the United States. The Comirnaty Vaccine is not widely available due to limited supply, as Pfizer also notes that "there is not sufficient approved vaccine [the Comirnaty] available for distribution to this population in its entirety at the time of the reissuance of this EUA."[33] Every COVID injection in America remains under the EUA law and thus people have the "option to accept or refuse" them. The fact that a Fact Sheet is still used for the Pfizer vaccine, as opposed to a Vaccine Information Statement for an approved vaccine[34], is proof of this.

66. Further, as 21 U.S.C.A. § 360bbb-3(c)(3) only permits the emergency use of products if "there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition, then if Pfizer has indeed "won the race"

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[31] Id.
[32] Id.
[33] See FDA, https://www.fda.gov/news-events/press-announcements/fda-approves-firstcovid-19-vaccine.
[34] All vaccine providers, public or private, are required by the National Vaccine Childhood Injury Act (NCVIA – 42 U.S.C. § 300aa-26) to give the appropriate Vaccine Information Statement (VIS) to the patient (or parent or legal representative) prior to every dose of specific vaccines defined by the Act. However, there is no COVID-19 Vaccine Information Statement.

against Moderna and J&J to "full FDA approval" for persons age 16, thus removing its own vaccine from the EUA, then logically the approval makes the Pfizer Comirnaty vaccine the *only* "adequate, approved, and available alternative to the other EUA COVID-19 vaccines for diagnosing, preventing, or treating COVID, the serious or life-threatening disease or condition", suggesting that Moderna and J&J's EUAs should now be void and their use denied until they are also fully approved. See **Complaint Ex. 4.**

67. There is a huge real-world difference between products approved under EUA compared with those the FDA has fully licensed.

68. Even after licensure, the clinical trials will not be complete for these products for more than a year (and, in the case of Pfizer, approximately 2 years). These products will remain experimental and investigational and the use of these products is a Phase IV post-market trial in which all recipients are part of the trial.[35]

EUA VACCINES SUBJECT TO CONSENT OR REFUSAL

69. The preceding Paragraphs are incorporated herein as if fully set forth.

70. Under 21 USCS § 360bbb-3, EUA products must be subject to consent or refusal. 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(I-III) of the Federal Food, Drug, and Cosmetic Act (FDCA) states:

> individuals to whom the product is administered are informed—
>
> (I) that the Secretary has authorized the emergency use of the product;
>
> (II) of the **significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown**; and
>
> (III) **of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and**

[35] https://www.cdc.gov/vaccines/basics/test-approve.html

of the alternatives to the product that are available and of their benefits and risks.

(Emphasis added).

71. This EUA provision was added to the FDCA in 2004 to provide the government with increased flexibility to respond to a chemical, biologic, nuclear, or radiation threat. When that pathway was created, special language was included for informational disclosures for individuals offered a medical product under an EUA. This is because specifically, under 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III), each individual must be informed "of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks." These are the aforementioned "Fact Sheets" cited herein and attached hereto as **Complaint Ex. 4.**

72. Although no court has interpreted 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III), the first segment of the subclause suggests that mandates are categorically prohibited, since each person must have "the option to accept or refuse."

73. But another legal interpretation is to view segment two as a qualifier to segment one. According to this interpretation, the provision as a whole could be interpreted to dictate that, although a person has the option to refuse an EUA product, refusal can come with "consequences", and under this second interpretation, the legality of a mandate is likely to hinge on how the term "consequences" is defined. Since the term is not defined in the statute, statutory interpretation principles dictate that the word should be defined in ordinary terms within the context of the statute. Allstate Life Ins. Co. v. Com., 617 Pa. 1, 52 A.3d 1077 (2012).

74. The entire subsection of 21 U.S.C. §360bbb-3(e) details conditions of authorization for EUA medical products, including the need to assess and disclose known risks and benefits and the need to monitor and report adverse events. There are no references to mandates or consent waivers. Rather, the subsection focuses on health-related measures that are conditions of administration. As such, in the context of a COVID-19 vaccine EUA, disclosure of "consequences" from opting to refuse a vaccine must be interpreted solely to include potential health consequences of refusal, such as an increased risk of acquiring or transmitting SARS-CoV-2 or an increased risk of disease burden from COVID-19, and not threatened termination from employment or other discipline.

75. The word "consequences" should not be defined broadly to encompass any adverse action that may be taken should a person decline vaccination. Under this interpretation, "consequences" could include health risks as well as adverse consequences related to work, access to education, use of public transportation, ability to shop in a store, board an airplane, and more.

76. As a practical matter, such a broad interpretation would open the possibility that public and private entities could institute mandates for EUA vaccines. If this interpretation were adopted, the FDCA would require that individuals be informed, prior to their decision on whether to accept an EUA medical product, of all possible health and non-health related consequences. It is unlikely that Congress would set this broad disclosure requirement on health care providers who are administering products available under an EUA. Such language is not presently found in the Fact Sheets. See **Complaint Ex. 4**.

77. Furthermore, if segment two of Section 360bbb-3(e)(1)(A)(ii)(III) opens the door to mandates, it would render meaningless the option stated in segment one. Under canons of

statutory interpretation, one segment of a statute should not be interpreted to obstruct another. Allstate, *supra*. Rather, provisions should be interpreted in a way that makes them compatible, not contradictory. In sum, it is most plausible that the mandatory disclosures of Section 360bbb-3(e)(1) (A)(ii)(III) are limited to health risks of refusing an EUA product during a public health emergency.

78. This interpretation is supported by the legislative history of the bill that created the EUA pathway. A review of the Congressional Record reveals no mention of allowing the government or private entities the ability to mandate administration of EUA products. Rather, EUAs consistently are characterized as a vehicle for providing access to promising, but unproven, medical products.

79. As the EUA Vaccine Fact Sheets require the detailing of the "consequences" for refusal of the vaccine under an EUA, they must also refer to any non-medical consequences, such as loss of employment, etc. They do not. See **Complaint Ex. 4.**

80. The United States District Court of the District of Columbia, held that the U.S. military could not mandate EUA vaccines to soldiers, and that the plaintiff soldiers had standing to seek injunctive relief in civilian court against mandated vaccination of an EUA anthrax vaccine. Doe #1 v. Rumsfeld, 297 F.Supp.2d 119 (2003). The court held: "...the United States cannot demand that members of the armed forces also serve as guinea pigs for experimental drugs." Id. at 135. Historically, no court has ever upheld a mandate for an EUA vaccine.

81. The EUA statute's prohibition on mandating EUA products is reinforced by a corresponding provision that allows the President, in writing, to waive the option of those in the U.S. military to accept or refuse an EUA product if national security so requires. 10

U.S.C. § 1107a(a)(1). That provision would be redundant if consent could be circumvented merely by telling a vaccine recipient that he or she is free to refuse the vaccine but nonetheless must suffer various adverse employment consequences violating the unconstitutional conditions doctrine.

82. The CDC itself has said that EUA products cannot be mandated. At the August 2020 meeting of the CDC's Advisory Committee on Immunization Practices, Dr. Amanda Cohn (the Committee's Executive Secretary), stated (beginning @1:14:37): "*I just wanted to add that, just wanted to remind everybody, that under an Emergency Use Authorization, an EUA, vaccines are not allowed to be mandatory. So, early in this vaccination phase, individuals will have to be consented and they won't be able to be mandated.*"[36]

83. Because EUA products are by definition experimental or investigational, and thus require the right to refuse. Under the Nuremberg Code (1947), the foundation of ethical medicine, no one may be coerced to participate in a medical experiment. The first principle of the Code states: "The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion.[37]" Consent of the individual is "absolutely essential."

[36] See "Advisory Committee on Vaccination Practices", CDC at https://www.cdc.gov/vaccines/videos/low-res/acipaug2020/COVID-19Supply-NextSteps_3_LowRes.mp4

[37] See "The Nuremberg Code", National Institutes of Health, https://history.nih.gov/display/history/Nuremberg+Code

84. There is no evidence of employers historically mandating vaccinations subject to EUAs prior to the COVID-19 vaccinations in 2021. This is because mandating COVID-19 vaccines under an EUA is legally and ethically problematic.

85. The first mandates regarding the vaccines at issue did not occur until nearly a year after release.

86. The act authorizing the FDA to issue EUAs requires the secretary of the Department of Health and Human Services (HHS) to specify whether individuals may refuse the vaccine and the consequences for refusal. Vaccine mandates are unjustified because an EUA requires less safety and efficacy data than full Biologics License Application (BLA) approval. Individuals would also likely distrust vaccine mandates under emergency use, viewing it as ongoing medical research.[38]

VACCINATION SAFETY MONITORING & SIDE EFFECTS

87. The preceding Paragraphs are incorporated herein as if fully set forth.

88. Potential side effects of all types of vaccinations are monitored, and a Federal system exists to catalog and address various remedies.

89. The Vaccine Adverse Event Reporting System[39] (VAERS), established in 1990, is a national early warning system to detect possible safety problems in U.S.-licensed vaccines. VAERS is co-managed by the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA).

90. VAERS accepts and analyzes reports of adverse events (possible side effects) after a person has received a vaccination. Anyone can report an adverse event to VAERS.

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[38] Journal of the American Medical Association, December 29, 2020, "Mandating COVID-19 Vaccines", Lawrence O. Gostin, JD; Daniel A. Salmon, MPH, PhD; Heidi J. Larson, PhD.
[39] See "Vaccine Adverse Event Reporting System (VAERS)", CDC at https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/index.html

Healthcare professionals are required to report certain adverse events and vaccine manufacturers are required to report all adverse events that come to their attention.[40] See **Complaint Ex. 4**.

91. VAERS is a "passive reporting system", meaning it relies on individuals to send in reports of their experiences to CDC and FDA. ""Underreporting" is one of the main limitations of passive surveillance systems, including VAERS."[41] It was estimated to account for only 1% of vaccine injuries[42]. "VAERS is not designed to determine if a vaccine caused a health problem, but is especially useful for detecting unusual or unexpected patterns of adverse event reporting that might indicate a possible safety problem with a vaccine. This way, VAERS can provide CDC and FDA with valuable information that additional work and evaluation is necessary to further assess a possible safety concern".[43]

92. The primary objectives of VAERS are to: Detect new, unusual, or rare vaccine adverse events; Monitor increases in known adverse events; Identify potential patient risk factors for particular types of adverse events; Assess the safety of newly licensed vaccines; Determine and address possible reporting clusters (e.g., suspected localized [temporally or geographically] or product-/batch-/lot-specific adverse event reporting); Recognize persistent safe-use problems and administration errors; and Provide a national safety

[40] See VAERS at https://vaers.hhs.gov/
[41] See "Guide to Interpreting VAERS Data", U.S. Dept. of Health & Human Services, at https://vaers.hhs.gov/data/dataguide.html
[42] See "Electronic Support for Public Health–Vaccine Adverse Event Reporting System (ESP:VAERS),Inclusive dates: 12/01/07 - 09/30/10. Lazarus, Ross, MBBS, MPH, MMed, GDCompSci, Grant Final Report, Grant ID: R18 HS 017045. See https://openvaers.com/images/r18hs017045-lazarus-final-report-20116.pdf
[43] See VAERS at https://vaers.hhs.gov/about.html

monitoring system that extends to the entire general population for response to public health emergencies, such as a large-scale pandemic influenza vaccination program.[44]

93. VAERS has successfully identified several rare adverse events related to vaccination. Among them are 1) An intestinal problem after the first vaccine for rotavirus was introduced in 1999; 2) Neurologic and gastrointestinal diseases related to yellow fever vaccine. Additionally, VAERS identified a need for further investigation of MMR association with a blood clotting disorder, encephalopathy after MMR, and syncope after immunization (Plotkin SA et al. Vaccines, 5th ed. Philadelphia: Saunders, 2008)[45].

94. OpenVAERS[46] is a search engine/data aggregator compiled weekly from the most recent data available from the US Dept. of Health & Human Services (HHS) for download from VAERS, which makes the collected VAERS information easier to observe and monitor. VAERS HHS releases updated data every Friday, which is data compiled for the previous week. [47]

95. The US Food & Drug Administration, in its safety surveillance capacity, is well aware of the potential for side effects of COVID-19 vaccinations. The FDA's Vaccines and Related Biological Products Advisory Committee October 22, 2020 Meeting Presentation addressed the "CBER Plans for Monitoring COVID-19 Vaccine Safety and Effectiveness" and provides a recorded video seminar of the meeting (originally streamed on October 22, 2020, a month prior to release of the COVID-19 vaccinations), which remains publicly available on the FDA's official Youtube account. The seminar contains

[44] See VAERS at https://vaers.hhs.gov/about.html
[45] https://www.historyofvaccines.org/content/articles/vaccine-development-testing-and-regulation cited by the CDC at https://www.cdc.gov/vaccines/basics/test-approve.html
[46] https://openvaers.com/.
[47] See https://openvaers.com/covid-data

slideshow presentations, which remain available from the FDA via direct download[48].

See **Complaint Ex. 6.**

96. The FDA presentation provides that, as of October 22, 2020, the "FDA Safety Surveillance of COVID-19 Vaccines: DRAFT Working list of possible adverse event outcomes" advised the following, anticipated medical conditions resulting from COVID-19 vaccination at pg. 16, which the FDA conceded was subject to change:

- Guillain-Barré syndrome [rare autoimmune disorder in which a person's own immune system damages the nerves, causing muscle weakness and sometimes paralysis].
- Acute disseminated encephalomyelitis [brief but widespread attack of inflammation in the brain and spinal cord that damages myelin, the protective covering of nerve fibers].
- Transverse myelitis [disorder caused by inflammation of the spinal cord].
- Encephalitis/ myelitis/ encephalomyelitis /meningoencephalitis/ meningitis/ encepholapathy [forms of brain and spinal cord inflammation].
- Convulsions/seizures [burst of uncontrolled electrical activity between brain cells (also called neurons or nerve cells) that causes temporary abnormalities in muscle tone or movements (stiffness, twitching or limpness), behaviors, sensations or states of awareness].
- Stroke [blood supply to part of the brain is interrupted or reduced, preventing brain tissue from getting oxygen and nutrients].
- Narcolepsy and cataplexy [loss of muscle tone].
- Anaphylaxis [a severe, potentially life-threatening allergic reaction].
- Acute myocardial infarction [myocardial necrosis (heart cell death) resulting from acute obstruction of a coronary artery].

[48] "Vaccines and Related Biological Products Advisory Committee October 22, 2020 Meeting Presentation", Steve Anderson, PhD, MPP, Director, Office of Biostatistics & Epidemiology, CBER. The original presentation was streamed on the FDA's website at https://www.fda.gov/media/143557. The 8 hour, 55 minutes presentation is posted in full at the FDA's Youtube account at https://www.youtube.com/watch?v=1XTiL9rUpkg&t=9220s. The slideshow detailing specific side effects is found at timecode 2:33:40, and the slideshow itself is available for download directly from the FDA at https://www.fda.gov/media/143557/download.

- Myocarditis/pericarditis [Myocarditis is inflammation of the heart muscle, while pericarditis is inflammation of the outer lining of the heart. In both cases, the body's immune system causes inflammation in response to an infection or some other trigger].

- Autoimmune disease [a condition in which your immune system mistakenly attacks your body].

- Deaths.

- Pregnancy and birth outcomes.

- Other acute demyelinating diseases [central nervous system (CNS) inflammatory demyelinating diseases, which are a group of disorders that include multiple sclerosis, acute disseminated encephalomyelitis, and neuromyelitis optica. These conditions may result in emergencies because of severe inflammatory destruction of CNS tissues or complications thereof].

- Non-anaphylactic allergic reactions.

- Thrombocytopenia [a condition consisting of a low blood platelet count. Platelets (thrombocytes) are colorless blood cells that help blood clot].

- Disseminated intravascular coagulation [disseminated intravascular coagulation (DIC) is a serious disorder in which the proteins that control blood clotting become overactive].

- Venous thromboembolism [a disorder that includes deep vein thrombosis (blood clotting in a deep vein) and pulmonary embolism (blood clotting in the lungs)].

- Arthritis and arthralgia/joint pain.

- Kawasaki disease [inflammation (swelling and redness) in blood vessels throughout the body, often found in children].

- Multisystem Inflammatory Syndrome, in Children.

- Vaccine enhanced disease [also known as "antibody-dependent enhancement" (ADE). ADE occurs when the antibodies generated during an immune response recognize and bind to a pathogen, but they are unable to prevent infection. Instead, these antibodies act as a "Trojan horse," allowing the pathogen to enter cells and exacerbate the immune response].[49]

[49] See **Complaint Ex. 6**. Pg. 16 of the slideshow shown in "Vaccines and Related Biological Products Advisory Committee October 22, 2020 Meeting Presentation", Steve Anderson, PhD, MPP, Director, Office of Biostatistics &

See **Complaint Ex. 6.**

97. Many of these side-effects have been reported by patients and doctors since the release of the EUA vaccines.

98. According to the CDC and its "Selected Adverse Events Reported after COVID-19 Vaccination", as of October 6, 2021, for COVID-19 vaccines issued in the United States from December 14, 2020, through October 4, 2021, VAERS received **8,390 US** reports of death among people who received a COVID-19 vaccine. See **Complaint Ex. 7.**

99. VAERS and OpenVAERS indicates the following reports of adverse events (possible side effects) incident to COVID-19 vaccinations (593,727 Total COVID-19 Vaccine only **US** Reports, through October 1, 2021) at **Complaint Ex. 8**:

- Deaths – 7,437
- Hospitalizations – 34,880
- Urgent Care – 74,520
- Doctor Office Visits – 111,694
- Anaphylaxis – 1,977
- Bells' Palsy – 2,574
- Miscarriages – 1,226
- Heart Attacks – 3,841
- Myocarditis/Pericarditis – 3,123
- Permanent Disabilities – 8,088
- Thrombocytopenia/Low Platelet – 1,165
- Life Threatening – 9,012
- Severe Allergic Reaction – 23,730
- Shingles – 6,202[50]

100. VAERS and OpenVAERS indicates the following reports of adverse events (possible side effects) incident to COVID-19 vaccinations (778,683 Total COVID-19 Vaccine

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Epidemiology, CBER", available for download directly from the FDA at https://www.fda.gov/media/143557/download.

[50] See also https://openvaers.com/covid-data

ALL (US and non-domestic) Reports[51], through October 1, 2021) at **Complaint Ex. 9 and 10:**

- Deaths – 16,310
- Hospitalizations – 75,605
- Urgent Care – 87,814
- Doctor Office Visits – 121,305
- Anaphylaxis – 7,141
- Bells' Palsy – 9,446
- Miscarriages – 2,415
- Heart Attacks – 7,868
- Myocarditis/Pericarditis – 8,689
- Permanent Disabilities – 23,712
- Thrombocytopenia/Low Platelet – 3,620
- Life Threatening – 17,619
- Severe Allergic Reaction – 30,631
- Shingles – 9,215[52]

101. VAERS/OpenVAERS likewise shows that marked increase in reports of alleged death resulting from *all* vaccinations (not just COVID vaccinations) as of late 2020 into 2021, coinciding with release of the COVID-19 vaccines. Reports of alleged deaths incident to all vaccinations did not exceed 1,000 per year from 1990 to 2020, until 2021 when they reached 16,598, a 3,587.47% increase from 2020. Note that while VAERS does not conclude causation, it is a passive reporting system, and this number likely underrepresents all potential adverse events (see **Complaint Ex. 9 and 10**):

- 1990 – 80
- 1991 – 166
- 1992 – 228
- 1993 – 234
- 1994 – 237

[51] See CDC, "Advisory Guide to the Interpretation of VAERS Data " at https://wonder.cdc.gov/wonder/help/vaers/VAERS%20Advisory%20Guide.htm - "VAERS occasionally receives case reports from US manufacturers that were reported to their foreign subsidiaries. Under FDA regulations, if a manufacturer is notified of a foreign case report that describes an event that is both serious and unexpected (in other words, it does not appear in the product labeling), they are required to submit it to VAERS. It is important to realize that these case reports are of variable data quality and completeness, due to the many differences in country reporting practices and surveillance system quality."

[52] See also https://openvaers.com/covid-data

- 1995 – 158
- 1996 – 151
- 1997 – 173
- 1998 – 172
- 1999 – 179
- 2000 – 212
- 2001 – 225
- 2002 – 187
- 2003 – 265
- 2004 – 208
- 2005 – 215
- 2006 – 220
- 2007 – 262
- 2008 – 333
- 2009 – 337
- 2010 – 319
- 2011 – 331
- 2012 – 316
- 2013 – 339
- 2014 – 358
- 2015 – 377
- 2016 – 437
- 2017 – 467
- 2018 – 535
- 2019 – 605
- 2020 – 423
- 2021 – 16,598[53]

102. The following is the alleged reported deaths related to all COVID-19 vaccination, per month, from December 2020 to September 2021 (as of October 12, 2021) at **Complaint Ex. 9 and 10**:

- December 2020 - 19
- January 2021 - 727
- February 2021 – 1,567
- March 2021 – 2,140
- April 2021 – 2,451
- May 2021 – 1,728
- June 2021 – 1,908
- July 2021 – 1,936

[53] https://openvaers.com/covid-data

- August 2021 – 1,867
- September 2021 – 1,944

103. The following is the alleged reported deaths related to COVID-19 vaccination, per manufacturer, as of October 12, 2021 at **Complaint Ex. 10**:

- Johnson & Johnson – 1,172
- Moderna – 4,017
- Pfizer – 11,074

104. The following is the alleged reported deaths related to COVID-19 vaccination, per sex, as of October 12, 2021 at **Complaint Ex. 10**:

- Men – 8,370
- Women – 7,095
- Unknown – 845

105. The following is the alleged reported deaths related to COVID-19 vaccination, per age, as of October 12, 2021 at **Complaint Ex. 10**:

- Age 0-24 – 113
- Age 25-50 – 828
- Age 51-65 – 1,682
- Age 66-80 – 3,566
- Age 81+ - 3,995
- Unknown Age at Death – 6,126

106. The following is the alleged reported hospitalizations related to COVID-19 vaccination, per manufacturer, as of October 12, 2021 at **Complaint Ex. 10**:

- Johnson & Johnson – 5,438
- Moderna – 18,675
- Pfizer – 51,304
- Unknown - 188

107. The following is the alleged reported urgent care visits related to COVID-19 vaccination, per manufacturer, as of October 12, 2021 at **Complaint Ex. 10**:

- Johnson & Johnson – 7,790
- Moderna – 28,439
- Pfizer – 51,359

- Unknown – 226

108. The following is the alleged reported doctor office visits related to COVID-19 vaccination, per manufacturer, as of October 12, 2021 at **Complaint Ex. 10**:

- Johnson & Johnson – 10,352
- Moderna – 47,553
- Pfizer – 63,168
- Unknown – 232

109. The following is the alleged reported Anaphylaxis cases related to COVID-19 vaccination, per manufacturer, as of October 12, 2021 at **Complaint Ex. 10**:

- Johnson & Johnson – 229
- Moderna – 1,378
- Pfizer – 5,526
- Unknown – 8

110. The following is the alleged reported Bell's Palsy cases related to COVID-19 vaccination, per manufacturer, as of October 12, 2021 at **Complaint Ex. 10**:

- Johnson & Johnson – 516
- Moderna – 2,314
- Pfizer – 6,595
- Unknown – 21

111. The following is the alleged reported Myocarditis/Pericarditis cases related to COVID-19 vaccination, per manufacturer, as of October 12, 2021 at **Complaint Ex. 10**:

- Johnson & Johnson – 207
- Moderna – 1,991
- Pfizer – 6,478
- Unknown – 0

112. As stated in the Recipient Fact Sheets, the vaccines could cause other side effects that remain unknown at this time due to their relatively recent development. Logically, one cannot be certain about the long-term effects of a vaccine that has not been in existence

for the long term and thus cannot have been studied over a span of years. See **Complaint Ex. 4.**

113. Since the issuance of the vaccines, numerous agencies and countries have issued warnings or pauses on their use of the vaccines due to these effects:

a. On April 20, 2021, the EU called for a J&J Covid-19 Vaccine Warning on Blood Clots, but maintained that the benefits of the vaccine outweighed the risks[54].

b. On May 3, 2021, Denmark became the first country to exclude J&J's COVID vaccine from its vaccination program over a potential link to blood clotting disorders.[55]

c. On September 29, 2021, Slovenia temporarily suspended the use of Johnson & Johnson's (J&J) COVID-19 vaccine after a 20-year-old woman who had recently received the single-dose shot died.

d. The European Medicines Agency's Pharmacovigilance Risk Assessment Committee (PRAC) recently concluded that the use of the J&J vaccine is possibly linked with vein clotting and an immune condition that causes the immune system to attack blood platelets. The committee also found that the use of the J&J and the AstraZeneca vaccines is linked to an immune condition that causes the body's immune system to target healthy platelets needed for normal blood clotting.[56]

e. The Moderna COVID-19 Vaccine received an EUA on December 18, 2020. On June 25, 2021, the FDA revised the patient and provider fact sheets regarding the suggested increased risks of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the tissue surrounding the heart) following vaccination.[57]. See **Complaint Ex. 4.**

f. On September 29, 2021, the Toronto City News reported that the Ontario provincial government recommended only the Pfizer-BioNTech (Comirnaty) vaccine be used in the 18 to 24-year-old age group due to a rare symptom caused by the Moderna (Spikevax) vaccine. The provincial government made the

[54] See "EU Calls for J&J Covid-19 Vaccine Warning on Blood Clots, but Says Benefits Outweigh Risks ", the Wall Street Journal, at https://www.wsj.com/articles/eu-agency-says-benefits-of-j-j-covid-19-vaccine-outweigh-risks-but-calls-for-blood-clot-warning-11618929685.

[55] See "Denmark ditches J&J COVID-19 shots from vaccination programme", Reuters, at https://www.reuters.com/world/europe/denmark-excludes-jj-shot-vaccine-programme-local-media-reports-2021-05-03/

[56] European Medicines Association, "Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 27-30 September 2021", https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-27-30-september-2021

[57] See "Moderna COVID-19 Vaccine", FDA at https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine

determination following an increase in the heart conditions known as pericarditis and myocarditis.[58].

g. On October 6, 2021, Yahoo News reported that Sweden's Public Health Agency recommended a temporary halt to the use of the Moderna COVID-19 vaccine among young adults, citing concerns over rare side effects to the heart. It indicated that the pause should be in force until December 1, explaining that it had received evidence of an increased risk of side effects such as inflammation of the heart muscle (myocarditis) and inflammation of the pericardium (pericarditis). According to the agency, the risk seemed especially tied to the second dose of the Moderna vaccine and was more prevalent among young men and boys, and in the weeks just following the second jab.[59].

h. Both mRNA vaccines (Pfizer's and Moderna's) contain polyethylene glycol (PEG), and J&J's vaccine contains polysorbate 80 - structurally similar ingredients associated with hypersensitivity reactions and anaphylaxis. Although the EUA mRNA vaccines are the first in widespread use to feature PEG, there are a number of approved vaccines that include polysorbate 80 - all of which document anaphylaxis in their package inserts[60].

i. In September 2021, two top FDA officials in charge of regulating and approving vaccines, Marion Gruber and Phil Krause, submitted their resignations in protest of the pre-emptive announcement by federal health officials concerning the recommendation for COVID-19 booster shots. Those officials later co-authored an article was published Sept. 13 in The Lancet medical journal asserting that there's no evidence the general population should get boosters. The article states that available COVID-19 vaccines offer strong protection against severe COVID-19 cases and symptoms, but that protection against symptomatic infection from the Delta variant has dropped. But they added that "current evidence does not … appear to show a need for boosting in the general population, in which efficacy against severe disease remains high." "Even if boosting were eventually shown to decrease the medium-term risk of serious disease, current vaccine supplies could save more lives if used in previously unvaccinated populations," the authors wrote. Booster shots could lead to more harmful side effects in the general population, which is a poorly understood phenomenon, they cautioned. "There could be risks if boosters are widely introduced too soon, or too frequently, especially with vaccines that can have immune-mediated side-effects (such as myocarditis, which is more common after the second dose of some mRNA vaccines, or Guillain-Barré syndrome, which has been associated with adenovirus-vectored COVID-19 vaccines)," the study said. If "unnecessary

[58] See "Ontario recommending Pfizer over Moderna vaccine for young adults", City News at https://toronto.citynews.ca/2021/09/29/ontario-moderna-vaccine-side-effect/
[59] See "Sweden halts use of Moderna's COVID vaccine in under 30s", Yahoo News at https://www.yahoo.com/news/sweden-halts-modernas-covid-vaccine-133409796.html
[60] See "Maintaining Safety with SARS-CoV-2 Vaccines", The New England Journal of Medicine, at https://www.nejm.org/doi/full/10.1056/NEJMra2035343

boosting causes significant adverse reactions" such as the aforementioned side-effects, the authors said, "there could be implications for vaccine acceptance that go beyond COVID-19 vaccines."

j. The FDA separately signaled boosters may not be needed. "There are many potentially relevant studies, but FDA has not independently reviewed or verified the underlying data or their conclusions," the FDA wrote. "Some of these studies, including data from the vaccination program in Israel, will be summarized during the September 17, 2021 [Vaccines and Related Biological Products Advisory Committee] meeting." Some studies, they said, have indeed shown the Pfizer mRNA vaccine has waning efficacy against the Delta variant or symptomatic infection. However, other studies have not, the FDA said. "Overall, data indicate that currently U.S.-licensed or authorized COVID-19 vaccines still afford protection against severe COVID-19 disease and death in the United States," FDA researchers wrote[61].

k. Thereafter, on September 22, 2021, the FDA amended the EUA for the Pfizer Vaccine to allow for use of a single booster dose, to be administered at least six months after completion of the primary series, only in: 1) individuals 65 years of age and older; 2) individuals 18 through 64 years of age at high risk of severe COVID-19; and 3) individuals 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19.[62] However, the FDA decision was a setback for Pfizer, which had asked the agency to make boosters available to everyone over age 16, six months after their second dose. TH FDA decision comes after a panel of doctors and other experts advising the FDA voted against the idea of making booster shots available that widely. The panel instead said that boosters should be given to people 65 and older, and to those most "at risk" of severe cases of COVID-19. Experts on the panel said there wasn't enough evidence showing the benefits of an extra vaccine dose for younger people. They also expressed concern that there wasn't enough safety data for younger adults, highlighting the risk of myocarditis, or heart inflammation, that has been seen at higher-than-usual levels in teenagers and 20-somethings who have been vaccinated. "The incremental benefit to the younger population really has not been demonstrated at all," Dr. Michael Kurilla, an infectious disease expert from the National Institutes of Health, said during the meeting. "I think we need to target the boosters right now specifically to the people who are likely to be at high risk, and it's an older population."[63]

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[61] https://www.fda.gov/media/152176/download

[62] See "FDA Authorizes Booster Dose of Pfizer-BioNTech COVID-19 Vaccine for Certain Populations", FDA at https://www.fda.gov/news-events/press-announcements/fda-authorizes-booster-dose-pfizer-biontech-covid-19-vaccine-certain-populations

[63] See "FDA authorizes boosters of the Pfizer-BioNTech coronavirus vaccine for older adults and others at high risk from COVID-19", Insider at https://www.businessinsider.com/fda-authorizes-booster-shot-pfizer-biontech-covid-coronavirus-vaccine-2021-9

l. Thereafter, on September 24, 2021, a panel of CDC advisers reviewed evidence and recommended that COVID boosters should be offered to people 65 and older, nursing home residents and those ages 50 to 64 who have risky underlying health problems, with the third dose given once they are at least six months past their last Pfizer shot. The panel voted against recommending that people can get a booster if they are ages 18 to 64 years and are health-care workers or have another job that puts them at increased risk of being exposed to the virus. But CDC Director Rochelle Walensky disagreed and put that recommendation back in, noting that such a move aligns with an FDA booster authorization decision earlier this week. The category she included covers people who live in institutional settings that increase their risk of exposure. Though "at risk" employment was left undefined, it would presumably include such as prisons or homeless shelters, as well as health care workers[64].

114. Note that "[v]accine development is a long, complex process, often lasting 10-15 years and involving a combination of public and private involvement."[65]. Typically, vaccine development includes six stages: (1) exploratory; (2) preclinical (animal testing); (3) clinical (human trials); (4) regulatory review and approval; (5) manufacturing; and (6) quality control[66].

115. The third phase typically takes place over years, because it can take that long for a new vaccine's side effects to manifest. Id.

116. The third phase must be followed by a period of regulatory review and approval, during which data and outcomes are peer-reviewed and evaluated by FDA. Id.

117. Finally, to achieve full approval, the manufacturer must demonstrate that it can produce the vaccine under conditions that assure adequate quality control.

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[64] See "CDC leader adds people with risky jobs to COVID booster list", AP News at https://apnews.com/article/coronavirus-pandemic-business-science-health-coronavirus-vaccine-95b8d9a432b60fe0e9713adf75dde0ee?utm_source=Twitter&utm_campaign=SocialFlow&utm_medium=APedium=AP

[65] See "Vaccine Development, Testing, and Regulation", The History of Vaccines at https://www.historyofvaccines.org/content/articles/vaccine-development-testing-and-regulation cited by the CDC at See "Vaccine Testing and the Approval Process", CDC at https://www.cdc.gov/vaccines/basics/test-approve.html

[66] *See* CDC, *Vaccine Testing and the Approval Process* (May 1, 2014), available at https://www.cdc.gov/vaccines/basics/test-approve.html.

118. FDA must then determine, based on "substantial evidence," that the medical product is effective and that the benefits outweigh its risks when used according to the product's approved labeling[67].

119. In contrast to this rigorous, six-step approval process that includes long-term data review, FDA grants EUAs in emergencies to "facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies, such as the current COVID-19 pandemic."[68]

120. EUAs allow FDA to make a product available to the public based on the best available data, without waiting for all the evidence needed for FDA approval or clearance. See Id.

121. The EUA statute states that individuals to whom the product is administered must be informed: (1) that the Secretary has authorized emergency use of the product; (2) of the significant known and potential benefits and risks of such use, and the extent to which such benefits and risks are unknown; and (3) of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks. 21 U.S.C. § 360bbb-3(e)(1)(A)(ii).

122. Studies of immunizations outside of clinical-trial settings began in December 2020, following the first EUA for a COVID vaccine. None of the precise EUA vaccines approved for use in the United States has been tested in clinical trials for its safety and efficacy on individuals who have recovered from COVID-19.

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[67] See FDA, "Understanding the Regulatory Terminology of Potential Preventions and Treatments for COVID-19", available at https://www.fda.gov/consumers/consumer-updates/understanding-regulatory-terminology-potential-preventions-and-treatments-covid-19

[68] See FDA, "Emergency Use Authorization for Vaccines Explained", available at https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained

123. The heightened risk of adverse effects results from "preexisting immunity to SARSCov-2 [that] may trigger unexpectedly intense, albeit relatively rare, inflammatory and thrombotic reactions in previously immunized and predisposed individuals."[69]

124. These vaccines were rushed to the market and not tested to the standards usually used to assess drugs or biologics. Given their novelty, there is no long-term safety data on these vaccines.

125. Short-term safety data is not being systematically collected over large populations (and, as noted herein, injury data is not being properly assessed).

126. Absolute risk reduction for the vaccines is only approximately 1%.[70]

127. The aforementioned alarming reports of injuries, including deaths potentially related to the vaccine are mounting and are not being properly assessed.

128. More scientists and doctors are speaking out about their concern and experiences. On May 24, 2021, a group of over 50 scientists, doctors, and public policy experts from around the world released a paper identifying risks associated with SARS-CoV-2 vaccines and highlighted the urgent need for independent oversight and monitoring of SARS-CoV-2 vaccine programs, which currently is lacking.[71]

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[69] See Angeli et al., SARS-CoV-2 Vaccines: Lights and Shadows, 88 EUR. J. INTERNAL MED. 1, 8 (2021).
[70] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7996517/pdf/medicina-57-00199.pdf and https://www.thelancet.com/journals/lanmic/article/PIIS2666-5247(21)00069-0/fulltext
[71] https://europepmc.org/article/PPR/PPR345192. After discussing some of the risks observed to date with respect to SARS-CoV-2 vaccines and the many concerning and unanswered questions surrounding SARS-CoV-2 vaccines, the authors state unequivocally: "If vaccination programs worldwide do not institute independent data safety monitoring boards (DSMB), event adjudication committees (EAC), and enact risk mitigation, we will call for a pause in the mass vaccination program. If DSMBs and EACs do not exist currently, as would be imperative for any investigational biomedical program, then vaccination should be immediately halted for those demographic groups at highest risk of vaccine-associated death or serious adverse effects, during the time it takes to assemble these boards and committees and commence their assessments. In the context of these concerns, we propose opening an urgent pluralistic, critical, and scientifically-based dialogue on SARS-CoV-2 vaccination among scientists, medical doctors, international health agencies, regulatory authorities, governments, and vaccine developers. This is the only way to bridge the current gap between scientific evidence and public health policy regarding the SARS-CoV-2 vaccines."

129. Vaccine manufacturers also have no incentive to ensure their vaccines are as safe as possible. Established in 1986 with the National Childhood Vaccine Injury Act (and reinforced by the 2005 Public Readiness and Emergency Preparedness Act (PREP)), vaccine makers cannot be sued even if they are shown to be grossly negligent. Under the PREP Act, manufacturers, healthcare providers, and government officials will be immune from liability for potential COVID-19 vaccine injuries and deaths. Compensation through its Countermeasures Injury Compensation Program is likely to be minuscule.

130. The National Vaccine Injury Compensation Program, also created in 1986, pits vaccine-injured claimants against HHS in an adversarial and usually unsuccessful process. In over three decades, the program has compensated only a third of the petitions filed. Even so, compensation awarded to date exceeds $4.5 billion. A Dec. 1, 2018 update by the U.S. Health Resources and Services Administration (HRSA) on the federal Vaccine Injury Compensation Program (VICP)[72] reported that the total amount of awards to children and adults who have been injured or died after receiving federally recommended childhood vaccines has surpassed $4 billion.[73]

131. Given the legal immunity provided by the PREP to vaccine manufacturers and distributors for anything less than willful misconduct[74], the County did not address any

[72] See "National Vaccine Injury Compensation Program", Health Resources and Services Administration at https://www.hrsa.gov/vaccine-compensation/index.html

[73] Health Resources and Services Administration. **Vaccine Injury Compensation Data**. Hhsa.gov Dec. 2018. See https://www.hrsa.gov/vaccine-compensation/data/index.html https://www.hrsa.gov/vaccine-compensation/data/index.html

[74] The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services (the Secretary) to issue a Declaration to provide liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures (Covered Countermeasures), except for claims involving "willful misconduct" as defined in the PREP Act. This Declaration is subject to amendment as circumstances warrant. The PREP Act was enacted on December 30, 2005, as Public Law 109-148, Division C, Section 2. It amended the Public Health Service (PHS) Act, adding Section 319F-3, which addresses liability immunity, and Section 319F-4, which creates a compensation program. These sections are codified at 42 U.S.C.

liability issues related to the vaccines, such as the liability of the County for the effects of its mandate, and whether an employee who becomes disabled or otherwise harmed after having received a vaccination, will be provided work related disability benefits and/or other methods of compensation (i.e. health insurance coverage, workers' compensation coverage, short term/long term disability coverage, life insurance, use of paid leave, etc.).

LACK OF IMMUNIZING EFFECT OF THE VACCINES

132. The preceding and subsequent Paragraphs are incorporated herein as if fully set forth.

133. According to the CDC, COVID-19 vaccinations do not provide immunity from COVID-19 infection and do not prevent transmission of COVID-19 to others, but instead act as an individual "therapeutic" treatment beneficial only for health of the subject employee to lessen the severity of symptoms[75]. The clinical trial study designs for COVID vaccines did not address transmission, but merely addressed reducing symptoms, as explained in the materials they submitted to the FDA to obtain Emergency Use Authorization[76].

134. In an August 5, 2021 televised interview with Wolf Blitzer of CNN, CDC Director Rochelle Walensky said that COVID-19 vaccines "can't prevent transmission" anymore despite working "exceptionally well." "Our vaccines are working exceptionally well. They continue to work well for Delta with regard to severe illness and death - they prevent it, but what they can't do anymore is prevent transmission," she told CNN's Wolf

247d-6d and 42 U.S.C. 247d-6e, respectively. See https://www.federalregister.gov/documents/2020/03/17/2020-05484/declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical-countermeasures

[75] See https://www.cnn.com/2021/08/05/health/us-coronavirus-thursday/index.html

[76] https://www.fda.gov/media/144245/download; https://www.fda.gov/media/144434/download; https://www.fda.gov/media/146217/download.

Blitzer. "So if you're going home to someone who is not vaccinated…I would suggest you wear a mask in public indoor settings," she continued.[77]

135. It is important to note that in the County's August 5 work rule, the County does not (yet) require masking for vaccinated persons. See **Complaint Ex. 1.**

136. Recent Israeli data found that those who had received the BioNTech Vaccine were 6.72 times more likely to suffer a subsequent infection than those with natural immunity[78].

137. On October 4, 2021, the Hill reported that a study released in The Lancet medical journal found that the efficacy of the Pfizer-BioNTech COVID-19 vaccine fell below 50 percent after about six months after the second dose. The data indicates the decline was not dependent on the strain of the coronavirus causing an infection. The Pfizer-funded study[79] found that Pfizer's vaccine was 88 percent effective in the first month after full vaccination but dropped to 47 percent effectiveness at about six months. The vaccine was also found to be highly effective against the delta variant, which was found to be over 90 percent effective in the first months before dropping to 53 percent effectiveness after four months. Researchers determined that the waning immunity had to do with the amount of time since an individual was given the second shot rather than due to the highly infectious delta strain. However, company representatives assert that the data also shows that the vaccines help *prevent hospitalizations and deaths*, and the third "booster" shot will offer reliable "*protection*" against the serious Delta variant[80].

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[77] See https://www.cnn.com/2021/08/05/health/us-coronavirus-thursday/index.html
[78] See David Rosenberg, Natural Infection vs Vaccination: Which Gives More Protection? ISRAELNATIONALNEWS.COM (Jul. 13, 2021), available at https://www.israelnationalnews.com/News/News.aspx/309762.
[79] https://www.thelancet.com/action/showPdf?pii=S0140-6736%2821%2902183-8
[80] https://thehill.com/policy/healthcare/575279-study-shows-pfizer-covid-19-vaccine-effectiveness-declines-after-six-months

138. On September 30, 2021, the Vermont Daily Chronicle reported[81] that, as of September 29, 2021, 88 % of all eligible Vermonters (age 12 and over) had been vaccinated with at least one shot. Yet 76% of the COVID-19 deaths in September 2021 were deaths of vaccinated persons. Specifically, out of 33 deaths in September, 25 were vaccinated, while 8 were unvaccinated. Expressed in percentages, 76% of Vermont Covid-19 fatalities were "breakthrough" cases.

139. On August 16, 2021 Science.org reported[82] that Israeli Minister of Health Nitzan Horowitz pushed for Israelis to obtain a third COVID-19 booster vaccination. Israel has among the world's highest levels of vaccination for COVID-19, with 78% of those 12 and older fully vaccinated, the vast majority with the Pfizer vaccine. Yet the country is now logging one of the world's highest infection rates, with nearly 650 new cases daily per million people. More than half are in fully vaccinated people, underscoring the extraordinary transmissibility of the Delta variant and stoking concerns that the benefits of vaccination ebb over time.

140. What is clear is that "breakthrough" cases are not the rare events the term implies.

141. Emerging data suggest that the Delta variant could spread more readily than other coronavirus variants among people vaccinated against COVID-19.[83]

142. A CDC study dated found that vaccinated people with breakthrough infections can spread the Delta variant. The study details a COVID-19 outbreak that started July 3 in

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[81] https://vermontdailychronicle.com/2021/09/30/76-of-september-covid-19-deaths-are-vaxxed-breakthroughs/
[82] https://www.science.org/news/2021/08/grim-warning-israel-vaccination-blunts-does-not-defeat-delta
[83] See "How do vaccinated people spread Delta? What the science says", Nature at https://www.nature.com/articles/d41586-021-02187-1. See also "Shedding of Infectious SARS-CoV-2 Despite Vaccination" at https://doi.org/10.1101/2021.07.31.21261387; see also "Delta variants of SARS-CoV-2 cause significantly increased vaccine breakthrough COVID-19 cases in Houston, Texas" at https://www.medrxiv.org/content/10.1101/2021.07.19.21260808v4; see also "Virological and serological kinetics of SARS-CoV-2 Delta variant vaccine-breakthrough infections: a multi-center cohort study" https://www.medrxiv.org/content/10.1101/2021.07.28.21261295v1

Provincetown, Mass., involving 469 cases. It found that three-quarters of cases occurred in fully vaccinated people. Massachusetts has a high rate of vaccination: about 69% among eligible adults in the state at the time of the study. It also found no significant difference in the viral load present in the breakthrough infections occurring in fully vaccinated people and the other cases, suggesting the viral load of vaccinated and unvaccinated persons infected with the coronavirus is similar. The CDC said the finding that fully vaccinated people could spread the virus was behind its move to change its mask guidance.[84]

143. A UC study found similarities in COVID viral loads between vaccinated and unvaccinated people.[85]

144. A CDC study dated September 21, 2021 says COVID-19 can spread in vaccinated: "Even with high vaccination rates, maintaining multicomponent prevention strategies (e.g., testing and masking for all persons and prompt medical isolation and quarantine for incarcerated persons) remains critical to limiting SARS-CoV-2 transmission in congregate settings where physical distancing is challenging."[86]

145. Science.org reported that as of August 15, 2021, 514 Israelis were hospitalized with severe or critical COVID-19, a 31% increase from just 4 days earlier. Of the 514, 59% were fully vaccinated. Of the vaccinated, 87% were 60 or older. "*There are so many breakthrough infections that they dominate and most of the hospitalized patients are*

[84] See "Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gatherings — Barnstable County, Massachusetts, July 2021", CDC at https://www.cdc.gov/mmwr/volumes/70/wr/mm7031e2.htm?s_cid=mm7031e2_w

[85] See "No Significant Difference in Viral Load Between Vaccinated and Unvaccinated, Asymptomatic and Symptomatic Groups Infected with SARS-CoV-2 Delta Variant", CDC at https://www.medrxiv.org/content/10.1101/2021.09.28.21264262v1.full.pdf

[86] See "Outbreak of SARS-CoV-2 B.1.617.2 (Delta) Variant Infections Among Incarcerated Persons in a Federal Prison — Texas, July–August 2021", CDC at https://www.cdc.gov/mmwr/volumes/70/wr/mm7038e3.htm

actually vaccinated," says Uri Shalit, a bioinformatician at the Israel Institute of Technology (Technion) who has consulted on COVID-19 for the government. "One of the big stories from Israel [is]: 'Vaccines work, but not well enough.'"

146. This lack of demonstrable immunity to the COVID-19 virus is recognized by the CDC in creatively amending the definitions of its operative language concerning vaccinations.

147. Since May 16, 2018, the CDC utilized the following definitions of the following terms related to vaccinations which convey the common understanding that the purpose of vaccines is *to provide/produce immunity to a specific disease*[87]:

> Immunity: Protection from an infectious disease. If you are immune to a disease, you can be exposed to it without becoming infected.
>
> Vaccine: A **product that stimulates** a person's immune system to **produce immunity to a specific disease, protecting the person from that disease.** Vaccines are usually administered through needle injections, but can also be administered by mouth or sprayed into the nose.
>
> Vaccination: The act of introducing a vaccine into the body to produce **immunity to a specific disease.**
>
> Immunization: A process by which a person becomes protected against a disease through vaccination. This term is often used interchangeably with vaccination or inoculation.

148. However, as of September 1, 2021[88], and after the issuance of the COVID-19 vaccines, the CDC amended the definitions of "vaccine" and "vaccination" in relevant part, as follows, eliminating the requirement of "immunity to" disease in favor of "protection from" disease, thus altering the general understanding of the method and purpose of vaccination reliable upon by medical professionals, lawmakers and the general public in

[87] See https://web.archive.org/web/20210826113846/https://www.cdc.gov/vaccines/vac-gen/imz-basics.htm
[88] See "Immunization: The Basics", CDC at https://www.cdc.gov/vaccines/vac-gen/imz-basics.htm

evaluating the merits of vaccinations. The CDC gave no explanation for the change in language:

> Vaccine: A **preparation that is used to stimulate** the body's **immune response against diseases**. Vaccines are usually administered through needle injections, but some can be administered by mouth or sprayed into the nose.
>
> Vaccination: The act of introducing a vaccine into the body to produce **protection from a specific disease.**

149. Dr. Anthony Fauci, the President's Chief Medical Adviser, said he did not have a "firm answer" when asked if *natural immunity* obtained from contracting and recovering from COVID-19 offered better protection from COVID-19 than the vaccine. On September 10, 2021, CNN's Dr. Sanjay Gupta asked Fauci whether people who have tested positive for the virus should still get vaccinated. He cited data from Israel in August suggesting people who recovered from COVID-19 had a lower risk of contracting the delta variant than those who got a full Pfizer vaccine. "You know, that's a really good point, Sanjay. I don't have a really firm answer for you on that. That's something that we're going to have to discuss regarding the durability of the response", Fauci said. The research from Israel, Fauci noted, did not address the durability that natural immunity offers, and he speculated that it is possible for a person to recover from COVID-19 and receive natural immunity, but then, that person might not be protected for nearly as long as the protection the vaccine offers. "I think that is something that we need to sit down and discuss seriously," he added[89].

[89] See https://www.yahoo.com/now/fauci-lacks-firm-answer-covid-200300992.html.

150. Almost 20 months into the pandemic, it is shocking that the Chief Medical Advisor to the President does not have a firm answer on the effectiveness of natural immunity, while alternatively promoting vaccine mandates.

151. Per the CDC data on US COVID-19 deaths among males and females, tabulated as of September 15, 2021, for males and females ages 18 through 55 (which is the average age range of the Association members), the rate of COVID-19-related deaths is between 0.002% and 0.132%. See **Complaint Ex. 11.**

COUNT I – INJUNCTIVE RELIEF (Permanent Injunction)

152. The preceding and subsequent Paragraphs are incorporated herein as if fully set forth.

153. The Plaintiff Association respectfully requests that this Honorable Court permanently enjoin any vaccine mandate issued or adopted by Allegheny County relating to COVID-19, including but not limited to, the December 1, 2021 COVID-19 vaccine mandate effective on employees of the Executive noticed by the County on September 29, 2021, for the reasons cited herein and herein above. Buffalo Twp. v. Jones, 571 Pa. 637, 813 A.2d 659 (2002).

154. Whether the preliminary injunction requested herein is granted or denied has no effect on whether a final, permanent injunction will ultimately be issued.

155. The County's mandate requires the Plaintiff Association's members to take a vaccine without their consent and against the expert medical advice of their doctors, thereby depriving them of their ability to refuse unwanted medical care.

156. The Supreme Court has recognized that the Ninth and Fourteenth Amendments protect an individual's right to privacy. A "forcible injection ... into a nonconsenting person's body represents a substantial interference with that person's liberty[.]" Washington v. Harper, 494 U.S. 210, 229 (1990).

157. The common law baseline is also a relevant touchstone out of which grew the relevant constitutional law. See, e.g., Cruzan v. Dir., Mo. Dep't of Public Health, 497 U.S. 261, 278 (1990) ("'At common law, even the touching of one person by another without consent and without legal justification was a battery'"). See W. Keeton, D. Dobbs, R. Keeton, & D. Owen, PROSSER AND KEETON ON LAW OF TORTS § 9, pp. 39-42 (5th ed. 1984).); Schloendorff v. Society of N.Y. Hosp., 211 N.Y. 125, 129-130, 105 N.E. 92, 93 (1914) (Cardozo, J.) ("Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages.").

158. Subsequent Supreme Court decisions have made explicit that the Constitution protects a person's right to "refus[e] unwanted medical care." Cruzan, 497 U.S. at 278; King v. Rubenstein, 825 F.3d 206, 222 (4th Cir. 2016) (recognizing same).

159. This right is "so rooted in our history, tradition, and practice as to require special protection under the Fourteenth Amendment." Washington v. Glucksberg, 521 U.S. 702, 722 n.17 (1997).

160. The Court has explained that the right to refuse medical care derives from the "well established, traditional rights to bodily integrity and freedom from unwanted touching." Vacco v. Quill, 521 U.S. 793, 807 (1997).

161. Coercing employees to receive a vaccine (whether approved under an EUA or fully by the FDA) for a virus that presents a near-zero risk of illness or death to them and which they are exceedingly unlikely to pass on to others because those employees already possess natural immunities to the virus, violates the liberty and privacy interests that the Ninth and Fourteenth Amendments protect.

162. "Government actions that burden the exercise of those fundamental rights or liberty interests [life, liberty, property] are subject to strict scrutiny, and will be upheld only when they are narrowly tailored to a compelling governmental interest." Does v. Munoz, 507 F.3d 961, 964 (2007).

163. Defendant County cannot show that it has a compelling interest, or even a rational basis, in coercing the Association's members into taking a COVID-19 vaccine, because the County has no compelling interest in treating employees with natural immunity any differently from employees who obtained immunity from a vaccine.

164. Defendant County cannot show that it has a compelling interest, or even a rational basis, in coercing the Association's members into taking a COVID-19 vaccine, because the County has no compelling interest in forcing employees to vaccinate against COVID-19 for the protection of others when the vaccines do not protect against transmission and infection.

165. Defendant County cannot show that the mandate is narrowly tailored to a compelling governmental interest. Any interest that the County may have in promoting immunity at does not extend to those employees who already have natural immunity—particularly those who can demonstrate such immunity through antibody screenings.

166. This provides evidence that the County is trying to exert control over individuals' personal health decisions, rather than attempting to promote a legitimate public health aim.

167. Indeed, the County's mandate acknowledges that it lacks a valid public health basis for its vaccine policy, in providing 80 hours of COVID-19 paid leave time to fully vaccinated employees who contract the COVID-19 virus or are otherwise quarantined for exposure. In other words, the County does not even pretend that the vaccine will provide immunity of infection and transmission to the vaccinated. Thus, the mandate infringes on Plaintiff Association's members' bodily autonomy with no public health justification.

168. Nor does the County provide any sound reasoning for a claim that its mandate will protect those who cannot be vaccinated. The County's justifications for its mandate are not only speculative, but logically incoherent.

169. If vaccinated people can also transmit the disease, as the County concedes, that only further undercuts any public health rationale for a vaccine mandate. It certainly drives home the arbitrary, nonsensical nature of the position that robust, naturally acquired immunity should not be recognized, while more limited immunity acquired through vaccination should be.

170. Plaintiff Association's members have suffered and will continue to suffer damage from Defendants' conduct.

171. There is no adequate remedy at law, as there are no damages that could compensate Plaintiff Association's members for the deprivation of their constitutional rights. They will suffer irreparable harm unless this Court enjoins Defendants from enforcing their mandate against said members.

172. Once even a single vaccination is administered, its effect is immediate and it cannot be removed from the body, or mitigated in effect thereafter.

173. If a vaccination causes an immediate or delayed side-effect which results in physical, mental, and other medical damages to the employee, while insurance claims may be available to provide payment of medical treatment and wage replacement, said benefits will not make the affected employee whole, in-fact, if they become permanently or otherwise indefinably disabled as a result. When weighed against the minor benefit such a vaccination would have on the general public (given that it does not prevent remission and infection), the risk of irreparable harm is far greater to the employee that the perceived benefit to the public. Any employee would prefer to remain healthy as opposed to disabled yet financially compensated.

174. Further, a single or double vaccination may not serve to comply with a progressively changing definition of full vaccination. The County's mandate did not address what "full vaccination" constitutes in regard to the availability of, or recommended use of, COVID "booster shots"[90] to improve the decreasing efficiency of the prior vaccinations.[91]

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[90] See Newsweek, "*CDC Declines to Change Definition of 'Fully Vaccinated' Amid Third Dose Authorization*", September 24, 2021. CDC Director Rochelle Walensky stated publicly in a White House COVID-19 briefing that, "We are not changing the definition *right now* of fully vaccinated. I think we need to have more experience with our third shot and have more people eligible or recommended to receive it before we change that definition that is something that we will be looking at in real-time". See https://www.newsweek.com/cdc-declines-change-definition-fully-vaccinated-amid-third-dose-authorization-1632565

[91] See The Atlantic, "*Fauci: Boosters for Everyone Will Keep America Healthy*", September 28, 2021. [Anthony S. Fauci, MD, NIAID Director, National Institute of Health (NIH)] moved the goalposts on what it means to be "fully vaccinated". For many months now, being "fully vaccinated" meant that you had to have two doses of either the Pfizer or Moderna mRNA vaccine, but now, according to Dr. Fauci, you're not fully vaccinated unless you get the third booster shot. "It is likely, for a real complete regimen, that you would need at least a third dose," Fauci told The Atlantic in an exclusive interview. "I've made it clear that my opinion has always been that I believe that a third-shot booster for a two-dose mRNA [vaccine] should ultimately and will ultimately be the proper, complete regimen," Fauci said. "The vaccine is very successful. The durability of it is something that's a subject of considerable discussion and sometimes debate." Fauci acknowledged that "we did not always know that a third dose would likely be an important part of the proper, complete regimen." Fauci also said that the boosters don't keep people alive, just from experiencing severe symptoms. "I think we should be preventing people from getting sick from COVID even if they don't wind up in the hospital," he said. https://www.theatlantic.com/health/archive/2021/09/fauci-boosters-everyone-will-keep-america-healthy/620220/."[

"Maintaining full vaccination" by implies mandating not just the current vaccines, or a boosters a decade or more in the future, but also any subsequent booster that is approved" and/or "recommended", even if only months from initial vaccination. This is "moving of the goalposts" that effects each person's health, as boosters may be different for each type of vaccine, and each individual person may not need a specific booster personally.

175. The continuing recommendations for "boosters" to the vaccines requires the employee to comply with an indefinite and undefined standard of "full vaccination" that will require ongoing maintenance of vaccine injections and the risk of compounding health effects upon the employees. The uncertainty about Dr. Fauci's redefining of "fully vaccinated", and Director Walensky's inclination to do the same, is the implications it has for those impacted by vaccine mandates. It is unknown if people who've had their required two doses of Pfizer and Moderna will not be considered fully vaccinated and face termination under such a vaccine mandate.

176. The mandate establishes a precedent to mandate not only vaccinations and boosters for this year and present virus strains, but for all strains ongoing into perpetuity.

177. BioNTech, which along with Pfizer, developed one of the most common COVID-19 vaccines in the world. BioNTech's Chief Executive Officer Ugur Sahin's told the Financial Times on October 4, 2021 that new vaccines might be necessary by 2022 to combat the "next generation" of COVID-19 variants, as the new strains of COVID-19, will likely be able to evade vaccines. "We have no reason to assume that the next generation virus will be easier to handle for the immune system than the existing

generation". "This year [a different vaccine] is completely unneeded. But by mid next year, it could be a different situation."[92]

178. The County's mandate also advised that employees who have submitted proof of vaccination will be entitled to up to eighty (80) hours of paid leave for reasons related to COVID-19: 1) if an employee tests positive for COVID-19; 2) if an employee is subject to a Federal, State, or local quarantine or isolation order related to COVID-19; or 3) if an employee has been advised by a health care provider to self-quarantine related to COVID-19 (with appropriate documentation provided by the employee). See **Complaint Ex. 2**. This is an explicit admission that the County anticipates its employees to become infected with COVID-19, and thus a risk to others, regardless of their individual full vaccination status, and as such, is an admission of the ineffectiveness of the vaccinations on immunity from the virus, and the prevention of spread of the virus to others, which is the focus of their mandate.

179. Asymptomatic Transmissions of COVID are too insignificant to warrant the mandate of a vaccine. Researchers at Nature Communications[93] and the Journal of the American Medical Association[94] both found that asymptomatic transmissions of Coronavirus are less than one (15) percent. In the case of JAMA, 0.7% of transmissions were among households, which would undoubtedly be lower in the general population or,

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[92] See "BioNTech chief predicts need for updated Covid vaccines next year", Financial Times,https://www.ft.com/content/d88457da-6bbc-4f07-82a6-4738aa845492; see also "CEO of COVID-19 Vaccine Maker Says Different Vaccine May Be Needed by Next Year", Epoch Times at https://www.theepochtimes.com/mkt_app/ceo-of-covid-19-vaccine-maker-says-different-vaccine-may-be-needed-by-next-year_4030976.html?utm_source=appan2028210?v=ul

[93] See "Post-lockdown SARS-CoV-2 nucleic acid screening in nearly ten million residents of Wuhan, China", Nature at https://www.nature.com/articles/s41467-020-19802-w

[94] See "Household Transmission of SARS-CoV-2A Systematic Review and Meta-analysis", Journal of American Medicine at https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2774102

hypothetically, a short time in a workplace where we are already spread apart, or an even shorter time in close proximity due to the infrequency or nature of such gatherings.

180. According to the CDC, COVID overall has a 99.74% survival rate. Among young people, that number is even higher. For people aged 18 to 29, the survival rate is 99.97%. Consider this low risk from COVID when deciding whether to take an experimental vaccine that causes significant side effects, including death[95]. See **Complaint Ex. 7.**

181. The particularly low mortality rate of the disease, but also its distribution by age, clearly denote that vaccination, whenever it becomes feasible, must be targeted. This percentage is over-evaluated for the time being (~2.5%): on the one hand, due to the over-representation of severely positive cases of the virus[96], and on the other, given that the death toll from COVID has also included the deaths of cases found positive for COVID but with other, underlying diseases (not the SARS respiratory syndrome). The CDC admits this, saying only 5% of deaths involving COVID-19 had COVID as the exclusive cause of death[97].

182. Per the CDC data on US COVID-19 deaths among males and females, tabulated as of September 15, 2021, for males and females ages 18 through 55 (which is the average age range of the Association members), the rate of COVID-19-related deaths is between 0.002% and 0.132%. See **Complaint Ex. 11.**

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[95] See "Provisional COVID-19 Deaths by Sex and Age", CDC at https://data.cdc.gov/NCHS/Provisional-COVID-19-Death-Counts-by-Sex-Age-and-S/9bhg-hcku/data

[96] See "Covid-19 fatality is likely overestimated", The BMJ at https://www.bmj.com/content/368/bmj.m1113.long

[97] See "Weekly Updates by Select Demographic and Geographic Characteristics", CDC at https://www.cdc.gov/nchs/nvss/vsrr/covid_weekly/index.htm

183. The Association avers that its membership includes individuals who are vaccinated against COVID-19 and those who are not. The Association estimates that roughly 156 of its current members are vaccinated against COVID-19 (76.8%), while 47 (23.1%) are not.

184. The Association avers that its membership also includes those who have recovered from COVID-19 infection, namely, 97 members have been given paid time off of work on salary continuation benefits under Act 17 of 2020, 35 Pa. Stat. and Cons. Stat. Ann. § 57A02 (West)[98]. Of those 97 members, 36 tested positive for COVID-19, while 61 of them were exposed to COVID-19, or considered symptomatic (with 14 of those 61 members ultimately testing negative).

185. The coronavirus does not present a significant risk of death to Association members employed at the County Police; despite positive infections, there were no COVID-19 hospitalizations or deaths of Association members since the outbreak in January 2020. See also **Complaint Ex. 11.**

186. Accordingly, the County's mandate, ostensibly intended to benefit others in the general public by requiring vaccination of its employees to prevent the spread of the virus to persons unvaccinated, has little to no relevance in protecting members of the general public from infection by "first responder" employees, when the public will not, in fact receive the intended benefit.

[98] Session of 2020. No. 2020-17. HB 1869. Act 17 of 2020 provides that employees who are covered under the Enforcement Officer Disability Benefits Act (a/k/a Heart & Lung Act, 53 P.S. § 637 et seq.) who contract or are diagnosed with Coronavirus Disease 2019 (COVID-19), as identified in the Proclamation of Disaster Emergency issued by Governor Wolf on March 6, 2020, published at 50 Pa.B. 1644 (March 21, 2020), or are subject to quarantine resulting from exposure to COVID-19, and by reason thereof are temporarily incapacitated from performing their duties, shall be compensated in accordance with section 1(a) of The Enforcement Officer Disability Benefits law (i.e., provided H&L wage benefits). Receipt of this benefit shall be limited to a maximum of sixty (60) days for each incident.

187. If that person cannot be vaccinated, the argument that a "first responder" must be vaccinated themselves in order to protect those unprotected others is greatly diminished when the mandated vaccines *provide only protection from the effects caused by more serious illness, and not prevention of transmission of the virus to others.*

188. Given that the vaccination is touted as "safe and effective", there is no reason that a person in the general public cannot obtain a vaccination to ensure their own protection. The Federal, State and Local governments have made the vaccine available to all who desire it, often at little to no cost.

189. In some cases, monetary enticements (such as monetary bonuses, tickets to lotteries, etc.) have been offered to entice vaccination. Such enticement would not be necessary if the vaccinations were truly effective against a deadly virus, as those unvaccinated would be clamoring for protection.

190. If an unvaccinated person cannot receive the injection (based upon medical consultation with their own provider) then it must be for their health-related reasons where vaccination will be harmful to them, or pursuant to religious objections, *thus justifying the merit and acceptance of medical and religious exemptions of employees from vaccinations as well.*

191. The factual, medical circumstances are not a binary choice between "vaccinated and unvaccinated". The County's mandate makes no effort to distinguish, or exempt from compliance, those employees with natural immunity to COVID-19, i.e. immunity (antibodies) most commonly developed after recovering from COVID-19 infection, or immunity otherwise obtained due to the employee's unique biochemistry[99].

[99] See. https://www.yahoo.com/now/fauci-lacks-firm-answer-covid-200300992.html.

192. Given that the vaccines are more therapeutic than preventative[100], there is no justifiable reason to terminate an employee who already recovered from the virus for failing to obtain the vaccine that does not prevent infection and transmission.

193. Given an employee's proof of naturally acquired immunity by way of antibody testing, the County cannot establish a compelling governmental interest in overriding the personal autonomy and constitutional rights of the Association's members and those who are similarly situated by forcing them either to be vaccinated or to suffer adverse professional consequences.

194. For similar reasons, the mandate constitutes an unconstitutional condition, because it is poorly calibrated to protect the public health, yet it imposes disproportionate risks on some of its targets. That renders the mandate an unlawful condition insufficiently germane to its purported purpose.

195. The County's mandate did not include confirmed acceptance any express exceptions to the mandate, such as a *bona fide* religious objection or an underlying medical condition rendering vaccination a threat to the employee's health.

196. The County's mandate does not address what constitutes sufficient proof of a medical or religious exemption for purposes of its mandate.

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[100] On October 4, 2021, the Hill reported that a study released in The Lancet medical journal found that the efficacy of the Pfizer-BioNTech COVID-19 vaccine fell below 50 percent after about six months after the second dose. The data indicates the decline was not dependent on the strain of the coronavirus causing an infection. The Pfizer-funded study (at https://www.thelancet.com/action/showPdf?pii=S0140-6736%2821%2902183-8) found that Pfizer's vaccine was 88 percent effective in the first month after full vaccination but dropped to 47 percent effectiveness at about six months. The vaccine was also found to be highly effective against the delta variant, which was found to be over 90 percent effective in the first months before dropping to 53 percent effectiveness after four months. Researchers determined that the waning immunity had to do with the amount of time since an individual was given the second shot rather than due to the highly infectious delta strain. However, company representatives assert that the data also shows that the vaccines help prevent hospitalizations and deaths, and the third "booster" shot will offer reliable protection against the serious Delta variant. https://thehill.com/policy/healthcare/575279-study-shows-pfizer-covid-19-vaccine-effectiveness-declines-after-six-months

197. The County's mandate did not address the availability of any reasonable accommodations/alternatives to vaccination, such as periodic testing and mask usage as the County implemented previously, or medical treatments/therapeutics. The County's mandate did not explain why the County no longer considers masking and testing sufficient (having utilized it publicly since the outbreak in 2020), nor did it explicitly confirm whether masking and testing would still be required of vaccinated employees in the future (despite CDC recommendations for masking of the vaccinated). If so, then such a policy is an admission of the ineffectiveness of the vaccinations on immunity from the virus, and the prevention of spread of the virus.

198. The County's mandate does not refer to any supporting medical evidence or justification beyond boilerplate statements of safety, effectiveness and appeals to authority aside from a rudimentary Q&A sheet. No CDC/FDA Fact Sheets (such as those submitted as exhibits hereto) were provided with the mandate notice. There is no citation to any specific studies, reports, findings or medical opinions indicating or supporting the County's specific reasoning for the mandate. As it is the County that is making this decision on behalf of all its Executive employees regardless of their individual medical circumstances, thus making the County and the employees liable for its potential effects, the mandate is per se unreasonable. It is precisely this type of information that must be presented and evaluated prior to such a decision being made, which the granting of an injunction will permit.

199. Forced Vaccination of an employee violates individual employees' Constitutional Rights in bodily autonomy and privacy in medical decisions, rights to work for a living and pursue his or her chosen occupation, as well as rights to procedural and substantive

due process and to equal protection, under the Fourteenth Amendment. Compulsory vaccination violates fundamental human rights, notably the right to prior, free and informed consent for medical interventions.

200. The County's mandate requires the Plaintiff Association's members to take a vaccine without their consent and against the expert medical advice of their doctors, thereby depriving them of their ability to refuse unwanted medical care.

201. The Supreme Court has recognized that the Ninth and Fourteenth Amendments protect an individual's right to privacy. A "forcible injection ... into a nonconsenting person's body represents a substantial interference with that person's liberty[.]" Washington v. Harper, 494 U.S. 210, 229 (1990). The common law baseline is also a relevant touchstone out of which grew the relevant constitutional law. See, e.g., Cruzan v. Dir., Mo. Dep't of Public Health, 497 U.S. 261, 278 (1990) ("'At common law, even the touching of one person by another without consent and without legal justification was a battery'"). See W. Keeton, D. Dobbs, R. Keeton, & D. Owen, *Prosser and Keeton on Law of Torts* § 9, pp. 39-42 (5th ed. 1984).); Schloendorff v. Society of N.Y. Hosp., 211 N.Y. 125, 129-130, 105 N.E. 92, 93 (1914) (Cardozo, J.) ("Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages.").

202. Subsequent Supreme Court decisions have made explicit that the Constitution protects a person's right to "refus[e] unwanted medical care." Cruzan, 497 U.S. at 278; King v. Rubenstein, 825 F.3d 206, 222 (4th Cir. 2016) (recognizing same).

203. This right is "so rooted in our history, tradition, and practice as to require special protection under the Fourteenth Amendment." Washington v. Glucksberg, 521 U.S. 702, 722 n.17 (1997).

204. The Court has explained that the right to refuse medical care derives from the "well established, traditional rights to bodily integrity and freedom from unwanted touching." Vacco v. Quill, 521 U.S. 793, 807 (1997).

205. Coercing employees to receive a vaccine (whether approved under an EUA or fully by the FDA) for a virus that presents a near-zero risk of illness or death to them and which they are exceedingly unlikely to pass on to others because those employees already possess natural immunities to the virus, violates the liberty and privacy interests that the Ninth and Fourteenth Amendments protect.

206. "Government actions that burden the exercise of those fundamental rights or liberty interests [life, liberty, property] are subject to strict scrutiny, and will be upheld only when they are narrowly tailored to a compelling governmental interest." Does v. Munoz, 507 F.3d 961, 964 (2007).

207. The U.S. Supreme Court in Roman Cath. Diocese of Brooklyn v. Cuomo, 141 S. Ct. 63, 208 L. Ed. 2d 206 (2020) recently acknowledged that the Jacobson v. Massachusetts[101] precedent concerning mandatory vaccination does not grant deference to governments on public health issues; strict scrutiny will clearly apply to enumerated rights and fundamental rights. J. Gorsuch's concurrence specifically talked about the available "opt-out" to vaccination for a low fine.

[101] The Supreme Court's 1905 Decision in Jacobson v. Massachusetts 197 U.S. 11 (1905) justified the imposition of one vaccine - smallpox - on adults "on an emergency basis" and under circumstances of "imminent danger." At the same time, the Jacobson decision established medical exemptions, reasoning that it "would be cruel and inhuman in the last degree" to vaccinate someone who was medically unfit. Jacobson also contained "robust cautionary

208. Defendant County cannot show that it has a compelling interest in coercing the Association's members into taking a COVID-19 vaccine, because the County has no compelling interest in treating employees with natural immunity any differently from employees who obtained immunity from a vaccine.

209. Defendant County cannot show that it has a compelling interest in coercing the Association's members into taking a COVID-19 vaccine, because the County has no compelling interest in forcing employees to vaccinate against COVID-19 for the protection of others when the vaccines do not protect against transmission and infection.

210. Defendant County cannot show that the mandate is narrowly tailored to a compelling governmental interest. Any interest that the County may have in promoting immunity does not extend to those employees who already have natural immunity—particularly those who can demonstrate such immunity through antibody screenings.

211. This provides evidence that the County is trying to exert control over individuals' personal health decisions, rather than attempting to promote a legitimate public health aim.

212. Indeed, the County's mandate acknowledges that it lacks a valid public health basis for its vaccine policy, in providing 80 hours of COVID-19 paid leave time to fully vaccinated employees who contract the COVID-19 virus or are otherwise quarantined for exposure. In other words, the County does not even pretend that the vaccine will provide immunity of infection and transmission to the vaccinated. Thus, the mandate infringes on the Association's members' bodily autonomy with no public health justification.

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language," calling attention to the potential for "arbitrary and oppressive" abuse of police power and warning against going "far beyond what was reasonably required for the safety of the public." Jacobson urged courts to be "vigilant to examine and thwart unreasonable assertions of state power." 197 U.S. 11 (1905)

213. Nor does the County provide any sound reasoning for a claim that its mandate will protect those who cannot be vaccinated. The County's justifications for its mandate are not only speculative, but logically incoherent.

214. If vaccinated people can also transmit the disease, as the County concedes, that only further undercuts any public health rationale for a vaccine mandate. It certainly drives home the arbitrary, nonsensical nature of the position that robust, naturally acquired immunity should not be recognized, while more limited immunity acquired through vaccination should be.

215. The mandate of forced vaccination removes the employee's ability to perform an individual medical cost/benefit analysis of a vaccination on their own health, with informed consent in consultation with their treating physician(s) privy to their medical history and profile. The mandate replaces it with the County's pre-determined "one-size fits all" political decision (one directly made by non-medical professionals), enforced through coercion by threat of termination of employment and denial of benefits.

216. Unconstitutional conditions case law often references the existence of varying degrees of coercion. According to that body of law, the County cannot impair Plaintiff' members' right to refuse medical care through subtle forms of coercion any more than it could through an explicit mandate. See, e.g., Koontz v. St. Johns River Water Mgmt. Dist., 570 U.S. 595 (2013) ("[U]nconstitutional conditions doctrine forbids burdening the Constitution's enumerated rights by coercively withholding benefits from those who exercise them"); Memorial Hosp. v. Maricopa Cty., 415 U.S. 250 (1974) (finding that state residency requirement impinged on the constitutionally guaranteed right to interstate travel, while lacking a compelling state interest, and thus was unconstitutional).

217. The Due Process Clause of the Fourteenth Amendment provides: "nor shall any state deprive any person of life, liberty, or property, without due process of law … ." U.S. Const., amend. XIV, sec. 1.

218. The Association's members possess both a liberty interest in their bodily integrity and a property interest in their careers/employment and a statutory interest in informed consent.

219. Unconstitutional conditions claims do not need to establish that a challenged government policy amounts to coercion. Instead, it is sufficient that the state/county policy burdens a constitutional right by imposing undue pressure on an otherwise voluntary choice with a nexus to the exercise of a constitutional right, i.e., the presence of some remaining voluntarism after new conditions are imposed on the exercise of a constitutional right does not stand as a barrier to establishing a successful unconstitutional conditions claim. This is especially true when a government actor couples an unconstitutional condition with a procedural system stacked against the right-holder. Speiser v. Randall, 357 U.S. 513 (1958).

220. The process the County has established in relation to taking COVID-19 vaccines poses dangers to the Association's members' health (and thus to their liberty interests) as well as threatening the members with penalties if they do not comply.

221. The County cannot by means of its mandate effectively flip the burden of proof and require the Association's members to prove that it is safe for them to perform their respective jobs while unvaccinated. And setting up such a process, which is what County's mandate does, thereby represents a concurrent procedural due process of law violation and an unconstitutional condition burdening their liberty interests to be free of unwanted medical interventions.

222. The County's mandate is not a mere initial presumption that vaccination is superior to natural immunity of that it prevents infection and transmission (a contention that would have to be borne out by the science in any event or else the County had no business adopting its mandate that the Association's members can try to overcome. The mandate is, in essence, a conclusive presumption (and a procedural due process of law violation) that vaccination is required (even as to vaccines of far-lesser efficacy), unless the risks of the vaccine to a particular recipient warrant a special exception.

223. The County has deemed all vaccines to be equally protective in the fictitious presumption it has established. There is no scientific basis for the suppositions that the County has built into its mandate.

224. The County did not address any liability issues related to the vaccines, such as the liability of the County for the effects of its mandate, and whether an employee who becomes disabled or otherwise harmed after having received a vaccination, will be provided work related disability benefits and/or other methods of compensation (i.e. health insurance coverage, workers' compensation coverage, short term/long term disability coverage, life insurance, use of paid leave, etc.).

225. For the foregoing reasons, the *de facto* presumptions the mandate establishes become another part of the County's procedural due process of law violations that run afoul of unconstitutional conditions doctrine.

226. In short, by allocating burden of proof responsibility to the Association's members, coupled with the County stacking the process deck with presumptions that the Association has shown are scientifically unwarranted, the County contravenes the Due Process Clause. See Perry v. Sinderman, 408 U.S. 592, 597 (1972) (holding that the government "may not deny a benefit to a person on a basis that infringes his constitutionally protected interests"); Wieman v. Updegraff, 344 U.S. 183, 192 (1952) ("We need not pause to consider whether an abstract right to public employment exists. It is sufficient to say that constitutional protection does extend to the public servant whose exclusion pursuant to a statute is patently arbitrary or discriminatory").

227. Regardless of whether Pfizer recently received full FDA approval for the Comirnaty Vaccine, the remaining vaccines mandated for use by the County have not. As Pfizer itself acknowledges, the Comirnaty Vaccine is not widely available in the United States. And despite its attempts to create equivalence between its Pfizer-BioNTech and Comirnaty Vaccines, the two are legally distinguishable. Thus, even after the Comirnaty Vaccine's approval, the mandates still forces individuals, including Plaintiff's members and those who are similarly situated, to take one of the EUA vaccines (or, presumably, one of the domestically unapproved World Health Organization ["WHO"] vaccines).

228. The Association members who do not comply with the mandate will be subject to termination by the County, which includes not simply the loss of wages, service credit and employment benefits, but also "employment status" for future employment, as a discharge discipline is usually utilized by the County for serious legal and/or moral offenses (theft, excessive force, conduct unbecoming, fraternization, contraband, etc.)

that will negatively affect future employment opportunities. This discipline is not usual for vaccination status, especially for EUA vaccines.

229. The mandate does not define "full vaccination". The County's mandate did not address what "full vaccination" constitutes, in regard to simple administration of the vaccination(s) by December 1, 2021, or the in-fact medical vaccination status achieved two weeks post-injection.

230. The deadline for Mandate Compliance December 1, 2021 is vague, arbitrary and capricious. The mandate provides no explanation (medical, political or economical) as to why that date, as opposed to a date earlier or later than, was selected for compliance.

231. The County's mandate did not address whether the County would discipline or discharge an employee who was willing to comply with the mandate for full vaccination, but could not be fully vaccinated in-fact by the County's deadline of December 1, 2021 due to factual or medical reasons (such as a side effect suffered post-first injection).

232. The County's mandated does not address what will constitute sufficient medical proof of full vaccination status.

233. The County's mandate did not address whether the County would make the vaccine available to employees (and at what cost, and to whom), and does not address whether their vaccinations would take place during working hours or non-work hours.

234. The only parties to this proceeding that would be subject to substantial harm caused by an injunction are the County and the Association members.

235. As police officers subject to the PLRA and Act 111, the Association and its members are legally prohibited from striking as they are afforded collective bargaining rights. 43 P.S. §217.1 *et seq.*; 43 P.S. §211.1 *et seq*. The County asserts that its decision to require

employee vaccination for COVID-19 is purely a managerial prerogative that it alone can make with no input from the Association or its members. As the Association has already placed the County's actions before the PLRB for purposes of an adjudication of unfair labor practices related to employment benefits subject to collective bargaining, that litigation will not be resolved by December 1, 2021, and maintaining the effect of the mandate deadline of December 1, 2021 substantially harms the Association and its members to protect those benefits. See **Complaint Ex. 3.**

236. The Association members who are not already vaccinated presently sanitize; wear Personal Protective Equipment (PPE)[102] including masks and gloves as needed; maintain social distancing to the extent possible; and are subject to weekly COVID testing, similar to the practice generally undertaken for nearly two (2) years. These employees can be protected through non-pharmaceutical interventions such as health screenings, wearing masks and quarantine. Thus, an injunction on the mandate will continue that practice, subject to the pending ULP Complaint thereon.

237. Further, given that the County, per its mandate, will nevertheless provide 80 hours of COVID-19 paid leave time to fully vaccinated employees who contract the COVID-19 virus or are otherwise quarantined for exposure, it is reasonable to conclude that the vaccinated employees may likewise be subject to work requirements of PPE, masking and social distancing and sanitization in the future; if not, such a work rule is discriminatory against unvaccinated employees without reasonable medical justification.

[102] Personal protective equipment, commonly referred to as "PPE", is equipment worn to minimize exposure to hazards that cause serious workplace injuries and illnesses. These injuries and illnesses may result from contact with chemical, radiological, physical, electrical, mechanical, or other workplace hazards. Personal protective equipment may include items such as gloves, safety glasses and shoes, earplugs or muffs, hard hats, respirators, or coveralls, vests and full body suits. See https://www.osha.gov/personal-protective-equipment.

238. If the percentage of the Association member/employees who refuse to comply with the mandate as of December 1, 2021 is sizeable (estimated to be 23% of the County Police Officer work force at present), then the functions of the County Police in providing public law enforcement service will be seriously adversely affected, affecting public safety.

239. It will be next to impossible to obtain a sufficient number new employees who are properly trained in law enforcement work. New officers may be rushed into positions before their training is complete, and existing hires will be subject to continual double or triple overtime shifts to cover for those shifts usually staffed by the unvaccinated employees. This creates an increased financial burden to the County and an increased risk to officer and public safety.

240. Further, the County has already invested considerable expense in the training of unvaccinated employees, so discharging them for vaccination status will harm the County even further, especially if any such discipline is later overturned with "make whole" afforded to the employees.

241. Accordingly, the disciplinary action that the County is using to leverage ostensibly "voluntary" compliance with its mandate is not proportional to the County's purported public health aims.

242. Plaintiff Association's members have suffered and will continue to suffer damage from Defendant County's conduct.

243. There is no adequate remedy at law, as there are no damages that could compensate the Association's members for the deprivation of their constitutional rights. They will suffer irreparable harm unless this Court enjoins Defendant County from enforcing their mandate against said members.

244. Even beyond its constitutional defects, the County's unlawful mandate is irreconcilable with and frustrates the objectives of the statute governing administration of medical products authorized for emergency use only. Pursuant to the Supremacy Clause of the United States Constitution, federal law overrides conflicting state law and action by agents of the County of Allegheny. Accordingly, the mandate is preempted by the EUA statute and must be enjoined.

245. The EUA Statute preempts the County's mandate. Defendant County's mandate requires the Association's members to receive a vaccine in order to continue working for the County without regard to their natural immunity or the advice of their doctors concerning their health conditions.

246. The Association's member must also divulge personal medical information to the County and are threatened with disciplinary action if they decline to comply with this arbitrary mandate.

247. The mandate thus coerces or, at the very least, unduly pressures, the Association's members into getting vaccines that FDA approved only for emergency use.

248. The United States Constitution and federal laws are the "Supreme Law of the Land" and supersede the constitutions and laws of any state. U.S. Const. art. VI, cl. 2.

249. "State law is pre-empted to the extent that it actually conflicts with federal law." English v. General Elec. Co., 496 U.S. 72, 79 (1990) (internal citations and quotation marks omitted).

250. Federal law need not contain an express statement of intent to preempt state law for a court to find any conflicting state action invalid under the Supremacy Clause. See Geier v. American Honda, 520 U.S. 861, 867-68 (2000). Rather, federal law preempts any state law that creates "an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Arizona v. United States, 567 U.S. 387, 399-400 (2012).

251. The EUA statute mandates informed and voluntary consent. See John Doe No. 1 v. Rumsfeld, No. Civ. A. 03-707(EGS), 2005 WL 1124589, *1 (D.D.C. Apr. 6, 2005) (allowing use of anthrax vaccine pursuant to EUA "on a voluntary basis"). See also 21 U.S.C. § 360bbb- 3(e)(1)(A)(ii).

252. It expressly states that recipients of products approved for use under it be informed of the "option to accept or refuse administration," and of the "significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown." Id.

253. Since the County's mandate (a political subdivision of the Commonwealth of Pennsylvania) coerces the Association's members by making enjoyment of their constitutionally and statutorily protected consent rights contingent upon receiving an experimental vaccine, it cannot be reconciled with the letter or spirit of the EUA statute. See 21 U.S.C. § 360bbb-3.

254. The conflict between the mandate and the EUA statute is particularly stark given that the statute's informed consent language requires that recipients be given the "option to refuse" the EUA product. That is at odds with the mandate effectively forcing the Association's members to sustain significant injury to their careers if they do not want to take the vaccine, i.e. the mandate frustrates the objectives of the EUA process. See Geier, 520 U.S. at 873 (citing Hines v. Davidowitz, 312 U.S. 52, 67 (1941)).

255. This Honorable Court must not ignore the plain statutory prohibition on mandating EUA products.

256. The FDA's Approval of the Comirnaty Vaccine does not save the mandate from preemption.

257. That the Comirnaty Vaccine has received full FDA approval does not foreclose the preemption argument presented herein, since this approval does not extend to the Pfizer-BioNTech Vaccine, which is actually available. Indeed, even Pfizer acknowledges that the two vaccines are "legally distinct." See **Complaint Ex. 4**.

258. The claim that the two vaccines are interchangeable comes from a Guidance document, which does not carry force of law[103].

[103] See Christensen v. Harris County, 529 U.S. 576, 587-88 (2000) ("Interpretations such as those in opinion letters—like interpretations contained in policy statements, agency manuals, and enforcement guidelines, all of which lack the force of law—do not warrant Chevron-style deference."); Appalachian Power v. EPA, 208 F.3d 1015, 1028 (D.C. Cir. 2000) (guidance documents that agencies treat as de facto law are void because they did not run the notice-and-comment gauntlet) (setting aside an agency guidance document in its entirety); see also Maple Drive Farms Ltd. v. Vilsack, 781 F.3d 837, 857 (6th Cir. 2015) (instructing USDA to carefully consider on remand whether its approach to the term "prior- converted wetlands" ran afoul of Appalachian Power).

259. The FDA cannot convert a legally distinct product that is available (the BioNTech vaccine) into a fully approved vaccine (Comirnaty) that is not yet widely available. The FDA, via a mere guidance document, is improperly trying to establish equivalence between what are two legally distinct vaccines. That is improper as a general matter of administrative law. It is yet more improper since it is a maneuver conducted to override federal statutory rights to informed medical consent.

260. The County cannot be permitted to rely on mere FDA-issued guidance documents, especially not where doing so would vitiate clear statutory rights.

261. Since the Comirnaty Vaccine, being the only FDA-approved vaccine, is not widely available, and certainly is not available to all members of the population, the EUA statute's sphere of preemption continues to apply to override the County's Mandate. Worse yet, no publicly released documents from the County indicate that the County has even considered the issue of federal preemption and whether the full approval granted to the unavailable Comirnaty Vaccine has any significance to the rights of the Association's members.

262. Just as Congress prohibited the federal government from mandating EUA products, the state governments cannot do so, for the Supremacy Clause dictates that the EUA statute must prevail over conflicting state law or policy.

263. Defendant County's Mandate is thus preempted by federal law. See U.S. Const. art. VI, cl. 2; see also Kindred Nursing Ctrs. Ltd P'ship v. Clark, 137 S. Ct. 1421 (2017) (holding that Federal Arbitration Act preempted incompatible state rule); Hughes v. Talen Energy Marketing, LLC, 136 S. Ct. 1288, 1297 (2016) ("federal law preempts contrary state law," so "where, under the circumstances of a particular case, the challenged state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" the state law cannot survive).

264. Defendant County's COVID-19 vaccine mandate is invalid pursuant to Article VI, Cl. 2 of the United States Constitution, and must be preliminarily and permanently enjoined.

265. In sum, the mandate violates both the constitutional and federal statutory rights of the Plaintiff Association's members because it undermines their bodily integrity and autonomy and conditions their employment on their willingness to take a medically unnecessary and experimental vaccine. Forcing the Association's members to take this vaccine will provide no discernible, let alone compelling, benefit either to Plaintiff or to the County of Allegheny. The unconstitutional conditions doctrine exists precisely to prevent government actors from clothing unconstitutional objectives and policies in the garb of supposed voluntarism when those actors fully intend and expect that the pressure they are exerting will lead to the targets of such disguised regulation succumbing to the government's will.

266. The "offending activity" in this matter is the County's unilateral imposition of a vaccine mandate and its deadline of December 1, 2021. Granting the injunction will pause the mandate and permit the matter to be addressed in litigation before an

irreversible action (i.e. vaccination) is taken, to insulate the Plaintiff Association's members from this pressure and to vindicate their constitutional and statutory rights.

267. In this case, the injunction will restore the parties to their status, which would be no different than that undertaken for nearly two (2) years. Thus, an injunction on the mandate will continue that practice, a practice recommended to abate the spread of COVID-19, subject to the pending ULP Complaint thereon.

268. The *status quo* is that the Association members who are not already vaccinated sanitize; wear Personal Protective Equipment (PPE)[104] including masks and gloves; maintain social distancing to the extent possible; and are subject to weekly COVID testing, as they have for nearly two years. Further, given that the County's mandate will nevertheless provide 80 hours of COVID-19 paid leave time to fully vaccinated employees who contract the COVID-19 virus or are otherwise quarantined for exposure, it is reasonable to conclude that the vaccinated employees may also be subject to work requirements of PPE, social distancing and sanitization.

269. The Association avers that their right to relief is clear, as aforesaid herein above.

270. The County cannot establish a compelling governmental interest in overriding the personal autonomy and constitutional rights of Plaintiff Association's members by forcing them either to be vaccinated or to suffer adverse professional consequences.

271. The Association avers that the injunction is necessary to avoid an injury that cannot be compensated by damages.

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[104] Personal protective equipment, commonly referred to as "PPE", is equipment worn to minimize exposure to hazards that cause serious workplace injuries and illnesses. These injuries and illnesses may result from contact with chemical, radiological, physical, electrical, mechanical, or other workplace hazards. Personal protective equipment may include items such as gloves, safety glasses and shoes, earplugs or muffs, hard hats, respirators, or coveralls, vests and full body suits. See https://www.osha.gov/personal-protective-equipment.

272. The Association avers that that greater injury will result if the court does not grant the injunction than if it does.

273. The Association lacks an adequate remedy at law to restrain the County from enforcing its COVID-19 vaccine mandate, in violation of the PLRA and Act 111, as referenced herein, such relief is necessary to prevent this legal wrong.

274. The Association notified the County of the filing of this Complaint. Notice was provided by in-person communication to Andrew F. Szefi, Esq., Solicitor for the County of Allegheny, on October 12, 2021, who agreed to acceptance of service thereof.

275. The Association requests an immediate hearing before this Honorable Court on its request for a permanent injunction, and shall file a supporting *Motion* and *Brief* to that end.

WHEREFORE, Plaintiff, Allegheny County Police Association (ACPA), respectfully requests that this Honorable Court enter an Order pursuant to Pa. R.C.P. No. 1531 and law, to permanently enjoin any vaccine mandate issued or adopted by Allegheny County relating to COVID-19, including but not limited to, the December 1, 2021 COVID-19 vaccine mandate effective on employees of the Executive noticed by the County on September 29, 2021, and to impose such relief as is necessary.

COUNT II – INJUNCTIVE RELIEF (Preliminary Injunction)

276. The preceding and subsequent Paragraphs are incorporated herein as if fully set forth.

277. The Plaintiff Association respectfully requests that this Honorable Court also preliminarily enjoin any vaccine mandate issued or adopted by Allegheny County relating to COVID-19, including but not limited to, the December 1, 2021 COVID-19

vaccine mandate effective on employees of the Executive noticed by the County on September 29, 2021, for the reasons cited herein and herein above. Pa. R.C.P. No. 1531.

278. A party seeking a preliminary or special injunction must satisfy six (6) essential requirements to obtain preliminary injunctive relief. Specifically, the party must show that: (1) the injunction is necessary to prevent immediate and irreparable harm that cannot be adequately compensated by damages; (2) greater injury would result from refusing an injunction than from granting it, and, concomitantly, issuance of an injunction will not substantially harm other interested parties in the proceedings; (3) a preliminary injunction will properly restore the parties to their status immediately prior to the alleged wrongful conduct; (4) the activity to be restrained is actionable, the right to relief is clear, and the wrong is manifest, or, in other words, the party seeking the injunction is likely to prevail on the merits; (5) the injunction is reasonably suited to abate the offending activity; and (6) a preliminary injunction will not adversely affect the public interest. Porter v. Chevron Appalachia, LLC, 204 A.3d 411, 416 (Pa. Super. 2019); Summit Towne Centre, Inc. v. Shoe Show of Rocky Mount, Inc., 573 Pa. 637, 828 A.2d 995 (2003); Allegheny Cty. v. Com., 544 A.2d 1305, 1307 (Pa. 1988).

279. As detailed herein above, the underlying circumstances of this mandate, when analyzed according to the six (6) requirements a preliminary injunction, demonstrate that all six prerequisites are met, justifying the Association's requested preliminary injunctive relief against the mandate.

280. The County cannot establish a compelling governmental interest in overriding the personal autonomy and constitutional rights of the Association's members by forcing them either to be vaccinated or to suffer adverse professional consequences.

281. The County's new "COVID-19 vaccine mandate" work rule changes the existing working conditions for the Association bargaining unit members. There is presently no COVID-19 vaccination requirement. Bargaining unit members are only required to wear masks and personal protective equipment, and to submit to COVID-19 testing as indicated herein above.

282. The imposition of the COVID-19 vaccination mandate upon the Association's members constitutes a mandatory subject of collective bargaining within the meaning of Act 111 and the PLRA, specifically Sections 6(1)(a) and (e).

283. The County did not bargain with the Association prior to implementing the aforementioned vaccination mandate, but acted unilaterally. This unilateral action constitutes an unfair practice in violation of Act 111 and Sections 6(1)(a) and (e) of the PLRA.

284. As a result of this policy change, the Association timely filed Charges of Unfair Labor Practices under the PLRA and Act 111 with the PLRB on September 30, 2021, alleging that the imposition of the COVID-19 vaccination mandate upon the Association's members constitutes a mandatory subject of collective bargaining within the meaning of PLRA and Act 111, specifically Sections 6(1)(a) and (e) because the County did not bargain with the Association prior to implementing the aforementioned vaccination mandate, but acted unilaterally. See **Complaint Ex. 3.**

285. The Association argues that the County is required to rescind the COVID-19 vaccination mandate unless and until it satisfies its collective bargaining obligation pursuant to Act 111 and the PLRA, and requested that the PLRB declare the unilateral imposition of the new vaccination mandate an unfair labor practice within the meaning of

Act 111 and Sections 6(1)(a) and (e) of the PLRA, direct the County to rescind the mandate and to cease and desist from engaging in such unlawful actions, and make the bargaining unit members whole for any and all losses sustained due to the unlawful action. All other appropriate relief is requested. All other appropriate relief was requested. See **Complaint Ex. 3.**

286. The PLRB confirmed receipt of the filing of the charge via its email system on September 30, 2021. See **Complaint Ex. 3.**

287. It is highly unlikely that the underlying labor action before the Labor Board addressing the Charges of Unfair Labor Practices will resolve before the County's vaccination mandate for unvaccinated Association members takes effect on December 1, 2021, upon which time employee disciplinary discharges are expected.

288. The PLRB does not possess the authority to enjoin an employer work rule, such as the vaccine mandate, prior to a full adjudication of the unfair practice charge. The Association is thus without an adequate remedy at law to compel the County to comply with its collective bargaining obligation prior to the commencement of the COVID-19 vaccination mandates.

289. This Honorable Court has broad discretion to grant a preliminary injunction so as to preserve the *status quo* as it exists before the vaccine mandate takes effect.

290. This Honorable Court may act on the basis of the averments of the pleadings or petition and may consider affidavits of the parties or third persons or any other proof which the court may require, including testimony, depositions, preliminary objections, and arguments of counsel. Pa. R.C.P. No. 1531.

291. The entry of a preliminary injunction is necessary in order to maintain the *status quo* and to prevent the invasion of the Association members' bodies via compelled vaccination pending the outcome of the PLRB hearing and adjudication process.

292. The Association avers that the injunction is necessary to prevent immediate and irreparable harm to the Association and its members caused by the vaccine mandate that cannot be adequately compensated by damages, as detailed herein above.

293. The Association avers that greater injury would result from refusing an injunction than from granting it, and, concomitantly, issuance of an injunction will not substantially harm other interested parties (such as the County) in these proceedings. Rather, the injunction will harm the County by potentially nearly halving its workforce if follows through on its threat to terminate the unvaccinated employees.

294. The Association avers that a preliminary injunction will properly restore the parties to their status immediately prior to the vaccine mandate.

295. The Association avers that the activity to be restrained, i.e. the mandate compelling vaccination, is actionable, the right to relief is clear, and the wrong is manifest, i.e., the Association is likely to prevail on the merits.

296. The Association avers that the injunction is reasonably suited to abate the vaccine mandate.

297. The Association avers that a preliminary injunction will not adversely affect the public interest, given the insufficiency of the vaccines to stop transmission and infection of COVID-19.

298. The County cannot show that their conduct was reasonable or that a defense exists to the Plaintiff's claims.

299. The Association will provide any bond required by this Honorable Court under Pa. R.C.P. No. 1531(b). The question of a proper amount of bond is within the discretion of this Honorable Court.

300. The Association requests an immediate hearing before this Honorable Court on its request for a preliminary injunction, and shall file a supporting *Motion* and *Brief* to that end.

WHEREFORE, Plaintiff, Allegheny County Police Association (ACPA), respectfully requests that this Honorable Court enter an Order pursuant to Pa. R.C.P. 1531 and law, to preliminarily enjoin any vaccine mandate issued or adopted by Allegheny County relating to COVID-19, including but not limited to, the December 1, 2021 COVID-19 vaccine mandate effective on employees of the Executive noticed by the County on September 29, 2021, and to impose such relief as is necessary, so as to permit a full adjudication of the unfair practice charge pending before the Pennsylvania Labor Relations Board.

REQUESTED RELIEF

WHEREFORE, based upon the foregoing, Plaintiff, Allegheny County Police Association (ACPA), respectfully requests that this Honorable Court enter an Order pursuant to Pa.R.C.P. 1531 and law, to preliminarily and permanently enjoin any vaccine mandate issued or adopted by Allegheny County relating to COVID-19, including but not limited to, the December 1, 2021 COVID-19 vaccine mandate effective on employees of the Executive noticed by the County on September 29, 2021, and to impose such relief as is necessary.

Respectfully submitted,

WELBY, STOLTENBERG,
CIMBALLA & COOK, LLC

By: _____
s/Ronald R. Retsch, Esquire
PA I.D. No. 92822
330 Grant Street,
Grant Building, Suite 2620
Pittsburgh, PA 15219
(412) 562-0111 (phone)
(412) 562-0675 (fax)
rretsch@wscc-law.com

Counsel for Plaintiff,
Allegheny County Police Association

Date: October 14, 2021

CERTIFICATE OF COMPLIANCE

I certify that this filing complies with the provisions of the *Public Access Policy of the Unified Judicial System of Pennsylvania: Case Records of the Appellate and Trial Courts* that require filing confidential information and documents differently than non-confidential information and documents.

Respectfully submitted,

WELBY, STOLTENBERG
CIMBALLA & COOK, LLC

By: _____
s/Ronald R. Retsch, Esquire
PA I.D. No. 92822
330 Grant Street,
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(412) 562-0111 (phone)
(412) 562-0675 (fax)
rretsch@wscc-law.com

Counsel for Plaintiff,
Allegheny County Police Association

Date: October 14, 2021

IN THE COURT OF COMMON PLEAS OF ALLEGHENY COUNTY, PENNSYLVANIA

ALLEGHENY COUNTY POLICE ASSOCIATION, Plaintiff, v. **COUNTY OF ALLEGHENY, PENNSYLVANIA,** Defendant.	**CIVIL DIVISION** **NO. _____**

ORDER

AND NOW, this _____ day of _____, 2021, pursuant to the Plaintiff Allegheny County Police Association (ACPA)'s *Complaint in Equity for Preliminary and Permanent Injunctions*, and it is hereby ORDERED that:

1. That the County's December 1, 2021 COVID-19 Vaccine Mandate infringes upon the Plaintiff ACPA's members' constitutionally protected right to protect their bodily integrity and autonomy and to refuse unnecessary medical treatment;
2. That the County's December 1, 2021 COVID-19 Vaccine Mandate represents an unconstitutional condition, especially in light of a set of explicit and implicit procedures that violate the Due Process Clause of the Fourteenth Amendment;
3. That the County's December 1, 2021 COVID-19 Vaccine Mandate is preempted under the Supremacy Clause because the mandate, a county/state program, conflicts with the federal EUA Statute; AND THEREFORE;
4. That effective immediately, the County of Allegheny is preliminarily and permanently enjoined from mandating COVID-19 vaccinations, including but not limited to, the

December 1, 2021 COVID-19 vaccine mandate effective on employees of the Executive noticed by the County on September 29, 2021.

In complying with their obligations under this Order, the County shall also comply in full with its obligations under all applicable Pennsylvania, Federal, and local laws, including those under the Pennsylvania Labor Relations Act and Act 111 of 1968, regarding the bargaining of mandatory subjects of bargaining and terms and conditions of employment with its employees, and nothing in this Order relieves the County of such obligations.

This Court shall retain jurisdiction over this matter.

BY THE COURT:

_____J.

VERIFICATION

I, Detective Kenneth Scanlon, verify that I am a current employee of the County of Allegheny Police, as well as the duly elected President of the Plaintiff, Allegheny County Police Association, and that I am authorized to make this verification on its behalf. I further verify that the statements made in the foregoing document are true and correct to the best of my knowledge, information and belief. I understand that false statements herein are made subject to the penalties of 18 Pa.C.S.§4904, relating to unsworn falsification to authorities.

s/Kenneth Scanlon

Date: October 14, 2021

ALLEGHENY COUNTY
ALWAYS INSPIRING

FOR IMMEDIATE RELEASE
August 5, 2021

Contact: Amie M. Downs
412-350-3711 (office)
412-327-3700 (cell)
amie.downs@alleghenycounty.us

Fitzgerald Announces Vaccination Requirement for New County Employees

Additional Measures in Place for Current Unvaccinated Employees

PITTSBURGH – County Executive Rich Fitzgerald today announced measures for unvaccinated county employees as COVID cases begin to increase again in our region. Beginning next week, all new hires will have to be vaccinated, current employees who are unvaccinated will be required to wear masks and will be tested regularly for COVID once protocols have been established.

Effective Monday, August 9, 2021, executive branch employees of Allegheny County, including contracted employees, who have not provided proof of vaccination will be required to wear face coverings that cover the person's mouth and nose when indoors at any county facility. The policy also applies when individuals are in any county vehicle when not alone, as well as outdoors in instances when physical distancing is not possible. Additionally, unvaccinated visitors to county facilities will also be asked to mask up when indoors. Signage to that effect will be in place beginning tomorrow with the policy also taking effect on Monday, August 9. Vaccinated employees and visitors may make their own choice regarding masking.

"Vaccination is the most effective tool that we have to prevent the spread of COVID-19 and to protect those who for reasons of age, health or other conditions cannot be vaccinated," said Fitzgerald. "As a government and essential service which has been open throughout the pandemic, with the vast majority of our employees here working, vaccination is the best way for to ensure that the public we serve is protected. With this new policy, the public can have confidence that the measures we are taking will protect their health and well-being."

Fitzgerald met yesterday with corporate, educational and health leaders from the region to share the county's policy related to the unvaccinated and discuss how employers, collectively, could encourage more vaccination and further protect employees and the constituencies of their organizations. Following the meeting, various entities provided statements of support for the efforts, and reiterated their own commitments in this same vein:

Duquesne University

> *Duquesne University applauds the leadership of County Executive Rich Fitzgerald in bringing together representatives of business, healthcare and higher education from throughout the region to solidify a plan for a safe return to normalcy in our community. Taking steps to ensure that the maximum number of individuals are vaccinated and that unvaccinated individuals wear masks and participate in testing is the best way to ensure the safety of the entire community. Duquesne intends to follow the guidance of the County Executive and the Health Department in order to ensure a complete return to normal campus operation in the upcoming fall semester.*

Carnegie Mellon University:

> We applaud and support the policies announced by Allegheny County Executive Rich Fitzgerald today to prevent the spread of COVID-19 in our region, and the County's policies for masking and physical distancing for unvaccinated individuals are in line with Carnegie Mellon's

EXHIBIT
C-1

own on-campus protocols. In addition to requiring vaccines for all students and holding vaccine clinics for faculty and staff – the majority of whom are fully vaccinated. With the delta variant on the rise, vaccination has never been more critical and CMU joins civic, corporate, educational and health leaders from across the region in encouraging individuals to receive their shots as soon as possible.

Highmark Health and Allegheny Health Network

Highmark Health and Allegheny Health Network fully support the County's efforts to further safeguard county employees and our community at large as the COVID-19 pandemic continues to evolve, and particularly as the impact of the Delta variant grows across the country. We believe strongly that everyone who is eligible for the vaccine in our community should be vaccinated, particularly healthcare professionals who are heightened risk of exposure to the virus and who are essential to our public health infrastructure. At Highmark Health and AHN, we are actively contemplating additional strategies that will help increase vaccine rates both in the general public and among our employees. Protecting our patients and caregivers, and helping to bring an end to the pandemic in our community have been the guiding principles of every step we have taken since the pandemic began, and they will continue to be so.

Pennsylvania Restaurant & Lodging Association:

The hospitality industry continues to prioritize the health and safety of employees and guests. We urge people to follow the health protocols and recommendations, including unvaccinated individuals wearing masks indoors. Higher vaccination rates are our best bet for containing the spread of COVID-19 and its variants, and we implore unvaccinated individuals who are eligible for the shot to get it.

Pittsburgh Penguins:

The Pittsburgh Penguins partnered with UPMC over the course of the pandemic to host public vaccination clinics at PPG Paints Arena and our UPMC Lemieux facility in Cranberry, and to safely reopen our arena to our fans. We appreciate the leadership of County Executive Rich Fitzgerald, and we join together with other Pittsburgh business leaders to support efforts to increase vaccination rates as the best path toward defeating the pandemic and protecting the safety and quality of life of our region.

Pittsburgh Tech Council:

We thank Allegheny County Executive Rich Fitzgerald for his pragmatic and steady leadership in helping to prevent the serious and deadly consequences associated with COVID19.

We know that countless lives have already been spared through the early success Allegheny County has achieved through vaccinations. For that reason, we applaud the efforts of our healthcare providers, volunteers and public health officials who have helped us achieve vaccination rates that far exceed the national average.

We are hopeful that we can work together to save lives by encouraging our friends and family members to consult their physicians about the benefits of vaccination. We are taking immediate steps in our organization to ensure that our employees and member companies are well protected from the serious outcomes from COVID. At a minimum, we will mirror the polices being adopted by Allegheny County effective today.

We are encouraging our members to support this as well.

University of Pittsburgh:

The University of Pittsburgh joins County Executive Fitzgerald and Allegheny County employers in recognizing vaccines as our most powerful tool—especially when combined with other effective infection control measures, such as masking and testing—for promoting community protection against COVID-19. In fact: Pitt's virus control program is designed to maximize the effectiveness of all these measures.

"We're grateful to this coalition of stakeholders who have all committed to taking steps to increase vaccination within their own organizations and further protect the health of our community," said Fitzgerald. "This is not a one-size-fits-all approach, but one where organizations have a variety of tools at their disposal that allows them to meet the needs of their own operations."

Fitzgerald also announced that beginning on August 9, individuals being made conditional job offers with the county will have to be vaccinated as a condition of employment, subject to applicable federal and state laws. The prospective employee will need to be fully vaccinated or have at least one shot of a two-shot series before beginning work. Any employee who does not receive the second shot within 30 days will have their probationary employment terminated.

The county is also in the process of finalizing a testing protocol and expects to begin COVID testing of unvaccinated employees within the next 30-60 days, or sooner as details are finalized. Testing will occur at least once a week and employees, again including contracted employees, will also be required to continue wearing a face covering.

Violations of the policy can result in progressive discipline, up to and including termination. The frequency of testing will be determined based on worksite. Additional measures to protect the public will be considered after a review of the data which will begin on October 1. Additional details on the plan are being finalized and will be announced at a later date.

###

Office of County Executive Rich Fitzgerald
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WELBY, STOLTENBERG, CIMBALLA & COOK, LLC
ATTORNEYS AT LAW

Eric Stoltenberg <estoltenberg@wscc-law.com>

FW: Employee COVID-19 Vaccination Requirement

Scanlon, Kenneth <Kenneth.Scanlon@alleghenycounty.us> Wed, Sep 29, 2021 at 3:35 PM
To: Eric Stoltenberg <estoltenberg@wscc-law.com>

Below is what we got County-wide regarding the mandate.

Detective Ken Scanlon #483

Allegheny County Police Department

General Investigations Section

875 Greentree Road

10 Parkway Center

Pittsburgh, PA 15220

V – 412.473.1208

M – 412.352.7035

F – 412.473.1377

kenneth.scanlon@alleghenycounty.us

From: HR, Notifications <HR.Notifications@AlleghenyCounty.US>
Sent: Wednesday, September 29, 2021 12:01 PM
Subject: Employee COVID-19 Vaccination Requirement

EXHIBIT C-2

Earlier today, Allegheny County Executive Rich Fitzgerald announced that in the interest of the health and safety of the county workforce and of the communities we serve, and in light of public health guidance regarding the most effective and

necessary defenses against COVID-19, all county employees under the executive branch are required to receive COVID-19 vaccination, subject to such exceptions as required by law.

Current county employees must show proof of their second dose of a two-dose COVID-19 vaccine, or proof of a one-dose vaccine on or before **December 1, 2021**. Employees who fail to submit proof of completed vaccination to their department Point of Contact (list of POCs attached) by December 1, 2021 will be subject to termination of employment.

Employees who have not submitted proof of completed vaccination to date will receive additional information, via USPS mail and hand-delivery at the workplace by their department management in the coming days. Also attached is a document with information about the vaccine to help address any concerns, and to provide links to additional resources for reference, including the CDC COVID Vaccine Website and the Allegheny County COVID-19 website:

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html

https://alleghenycounty.us/Health-Department/Resources/COVID-19/COVID-19.aspx

Please be advised that employees who have submitted proof of vaccination will be entitled to up to eighty (80) hours of paid leave for reasons related to COVID-19: 1) if an employee tests positive for COVID-19; 2) if an employee is subject to a Federal, State, or local quarantine or isolation order related to COVID-19; or 3) if an employee has been advised by a health care provider to self-quarantine related to COVID-19 (with appropriate documentation provided by the employee).

[Quoted text hidden]

2 attachments

Copy of Department Points of Contact List.pdf
94K

COVID-MythvsTruth_HR.pdf
755K

ALLEGHENY COUNTY

COVID-19 VACCINE Myth vs Fact

Myth	Fact
There's no point in getting vaccinated because you still have to wear a mask.	Vaccines protect you from getting seriously ill. Masks are still needed in certain settings to protect you AND to protect those around you who have not been or cannot be vaccinated—and there are some people who cannot be vaccinated because of age, health conditions or other reasons.
Vaccines cause infertility.	No evidence supports this. The truth is that COVID-19 vaccines do not affect the fertility of women who are seeking to become pregnant.
The vaccines don't work against variants.	Actually, research shows that the U.S. vaccines are highly effective against variants, which is very encouraging. There is ongoing surveillance tracking vaccination breakthrough cases and new variants to make sure that remains so.
If you've had COVID-19, you don't need to get vaccinated.	Even if you've had COVID, getting the vaccine is beneficial by bolstering your immune response to the virus. The immune response from the vaccine is stronger and longer lasting than natural infection.
Young people don't need to get vaccinated.	Everyone eligible should get vaccinated. It's true that young, healthy children and adults generally are not severely sickened by COVID-19, but they certainly contribute to the virus's spread. Also some young people do get very sick and have long term symptoms. Again, EVERYONE should get vaccinated. Not only for yourself, but for your parents and grandparents, and other young people with underlying conditions.
The vaccines were rushed, and therefore were developed too quickly for anyone to be certain they are safe.	The science is solid. These vaccines are rooted in well-established technologies used to develop other vaccines. They underwent extensive testing in 10s of thousands of people. They have been now given to millions across the country. This vaccine is safer than the COVID-19 virus, which contributed to the death of nearly 2132 Allegheny County residents.

FOR MORE INFORMATION ON THE COVID VACCINE, VISIT THESE SITES BELOW:

CDC COVID Vaccine Website
cdc.gov/coronavirus/2019-ncov/vaccines/index.html

Allegheny County COVID Website
alleghenycounty.us/COVID

Everyone in the United States 12 years and older is eligible for a COVID-19 vaccine. Getting vaccinated is fast, easy, and free.

Visit vaccines.gov for more information.

Ways to find a COVID-19 vaccine near you:

- **Search** gov
- **Text** your ZIP code to 438829
- **Call** 1-800-232-0233

Department Points of Contact			
Department	**Division**	**POC**	**POC Email**
Administrative Services	Veterans	Boddorf, Dwight	Dwight.Boddorf@AlleghenyCounty.US
Administrative Services	Purchasing and Supplies	Stockman, Kelly	Kelly.Stockman@AlleghenyCounty.US
Administrative Services	Call Center	Cipcic, Michele D.	Michele.Cipcic@AlleghenyCounty.US
Administrative Services	Elections	Calhoun, Caitlin C.	Caitlin.Calhoun@AlleghenyCounty.US
Administrative Services	Real Estate	Haus, Kristina	Kristina.Haus@AlleghenyCounty.US
Administrative Services	Property Assessments	Mangan, Donna	Donna.Mangan@AlleghenyCounty.US
Administrative Services	Special Events	Dowd, Kelsey	Kelsey.Dowd@AlleghenyCounty.US
Administrative Services	Admin, W&M, Records, Mailing, Print Shop	Arthur, Natalie	Natalie.Arthur@AlleghenyCounty.US
Budget and Finance		Buzzard, Gina	Gina.Buzzard@AlleghenyCounty.US
Controller		Martini, Rita	Rita.Martini@AlleghenyCounty.US
County Council		Roka, Sarah	Sarah.Roka@alleghenycounty.us
County Executive		Dietz, Sonya	Sonya.Dietz@AlleghenyCounty.US
County Manager		Pellegrini, Heather	Heather.Pellegrini@AlleghenyCounty.US
County Solicitor		Daly, Kimberly	Kimberly.Daly@AlleghenyCounty.US
Court of Common Pleas		Patterson Kathleen	Kathy.Patterson@alleghenycourts.us
Court Records		Bredl, David	David.Bredl@AlleghenyCounty.US
District Attorney		Hudson, Jacki	JHudson@AlleghenyCountyDA.us
Economic Development		Mascio, John P.	John.Mascio@AlleghenyCounty.US
Emergency Services		Linkosky, Kate	Kate.Linkosky@AlleghenyCounty.US
Equity and Inclusion		Edmonds, Lisa	Lisa.Edmonds@alleghenycounty.us
Facilities Management		DiNardo, Nancy	Nancy.DiNardo@AlleghenyCounty.US
Health		Barham, Melonye	Melonye.Barham@AlleghenyCounty.US
Human Resources		Molnar, Patricia	Patricia.Molnar@AlleghenyCounty.US
Human Services		Camerlin, Cathy	Catherine. Camerlin@AlleghenyCounty.us
Human Services		Talley, Amber	Amber.Talley@AlleghenyCounty.us
Information Technology		Kosco, Michael A.	Mike.Kosco@AlleghenyCounty.US
Jail		Pratt, Phillip	Phillip.Pratt@AlleghenyCounty.US
Jail		King, Patricia	Patricia.King@AlleghenyCounty.US
Juvenile Court Placement		Patterson Kathleen	Kathy.Patterson@alleghenycourts.us
Kane Regional Centers	Central	Ulyas, Rona	Rona.Ulyas@AlleghenyCounty.US
Kane Regional Centers	Glenn Hazel	Casie Shepard	Casie.Shepard@AlleghenyCounty.US
Kane Regional Centers	McKeesport	Kelly Serena	Kelly.Serena@AlleghenyCounty.US
Kane Regional Centers	Ross	Morreale, Rita	Rita.Morreale@AlleghenyCounty.US
Kane Regional Centers	Scott	Caprino, Heather	Heather.Caprino@AlleghenyCounty.US
Medical Examiner		Mirt, Eve	Eve.Mirt@AlleghenyCounty.US
Parks		Mott, Angela	angela.mott@alleghenycounty.us
Police		Ferguson, Lewis	Lewis.Ferguson@AlleghenyCounty.US
Police	Shuman Guards	Packer, Jeremy P.	Jeremy.Packer@AlleghenyCounty.US
Police	Courthouse Guards	Huffman, Michael	Michael.Huffman@AlleghenyCounty.US
Public Defender		Camerota, Tracy	Tracy.Camerota@AlleghenyCounty.US
Public Works		Eckle, Sean	Sean.Eckle@AlleghenyCounty.US
Sheriff		Ashbaugh Meghan	MParker@alleghenycourts.us
Shuman Center		Reese-McGhee, Lillian	Lillian.Reese-McGhee@alleghenycounty.us
Treasurer		Boyle, William E.	William.Boyle@AlleghenyCounty.US

Darnell Scoggins

From: LI, PLRB-Filing <RA-LIPLRB-FILING@pa.gov> on behalf of LI, PLRB-Filing
Sent: Thursday, September 30, 2021 10:50 AM
To: Darnell Scoggins
Subject: Auto Response

Your submission has been received by the Pennsylvania Labor Relations Board. Please note that this email account is reserved for filings with the PLRB only. Questions or other assistance should be directed to the PLRB's main telephone number at (717) 787-1091.

EXHIBIT
C-3

WELBY STOLTENBERG CIMBALLA & COOK, LLC
ATTORNEYS AT LAW

Sean T. Welby*
Eric C. Stoltenberg
Ian J. Blynn*
Richardson Todd Eagen*
Christopher J. Cimballa
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Christopher J. Cook*
Susan M. Pickup

330 Grant Street
The Grant Bldg., Suite 2620
Pittsburgh, PA 15219
Telephone 412-562-0111
Fax 412-562-0675

*Harrisburg Office
4785 Linglestown Road, Suite 100
Harrisburg, PA 17112
Telephone 717-234-0111
Fax 717-234-8964

Writer email:
estoltenberg@wscc-law.com

September 30, 2021

VIA EMAIL ONLY
RA-LIPLRB-FILING@PA.GOV
Nathan F. Bortner, Secretary
Pennsylvania Labor Relations Board
PA Department of Labor & Industry
651 Boas Street, Room 418
Harrisburg, PA 17121-0750

RE: Allegheny County Police Association
and
County of Allegheny
Vaccines ULP

Dear Secretary Bortner:

Enclosed for filing is a copy of the Charge of Unfair Labor Practices in the above matter. Thank you for your attention to this matter.

Very truly yours,

Eric C. Stoltenberg, Esquire

ECS/dps
Enclosure

cc: Kenneth Scanlon, ACPA (via email – w/enc)

CHARGE OF UNFAIR LABOR PRACTICE(S) UNDER THE PENNSYLVANIA LABOR RELATIONS ACT AND ACT 111

Allegheny County Police Association

COMPLAINANT

v.

County of Allegheny

RESPONDENT

DO NOT WRITE IN THIS SPACE
CASE NO.
DATE FILED

TO THE HONORABLE, THE MEMBERS OF THE PENNSYLVANIA LABOR RELATIONS BOARD:

COMPLAINANT INFORMATION

Allegheny County Police Association
Employe, Employe Organization or Employer

Eric C. Stoltenberg — Counsel
Name of Person filing charge on behalf of Complainant — Title

330 Grant Street, Suite 2620
Address

Pittsburgh — Pa — 15219
City — State — Zip

(412) 562-0111
Telephone

HEREBY CHARGES THAT

RESPONDENT INFORMATION

County of Allegheny
Employer, Employe Organization or Employe alleged to have committed unfair labor practice(s)

c/o Diego Correa, Esquire, 445 Fort Pitt Boulevard, Suite 300
Address

Pittsburgh — Pa — 15219
City — State — Zip

(412) 350-1172
Telephone

HAS ENGAGED IN UNFAIR LABOR PRACTICE(S) CONTRARY TO THE PROVISIONS OF THE PENNSYLVANIA LABOR RELATIONS ACT, SECTION 6 AS FOLLOWS:

Choose one:	Choose all that apply:	
☑ subsection (1)	☑ clause (a)	☐ clause (d)
○ subsection (2)	☐ clause (b)	☑ clause (e)
	☐ clause (c)	☐ clause (f)

☐ Check here if more than one respondent and list on separate sheet.

☐ Check here if a grievance relating to this issue has been filed and enclose three (3) copies of the grievance and one (1) copy of the Collective Bargaining Agreement to assist in review of this charge.

FAILURE TO ENCLOSE THESE DOCUMENTS WILL CAUSE A DELAY IN PROCESSING.

SPECIFICATION OF CHARGES

Set forth all of the events alleged to constitute the unfair labor practice(s). Include specific facts, dates, names, addresses, place of occurrence, and other relevant facts. If additional space is needed, please continue on additional sheet(s).

See Attached Specification of Charges

WHEREFORE, the Complainant respectfully requests the Pennsylvania Labor Relations Board to enter the charge upon the Docket of the said Board and to issue and cause to be served upon the Respondent above named a Complaint stating the charge(s) of unfair labor practice(s).

COMMONWEALTH OF PENNSYLVANIA :
: ss
COUNTY OF ALLEGHENY :

On this 30TH day of SEPTEMBER, 20 21, before me, a NOTARY PUBLIC, in and for said County and State, personally appeared ERIC C. STOLTENBERG who being duly sworn according to law, deposes and says that he/she is the person filing the foregoing CHARGE OF UNFAIR LABOR PRACTICE(S) and is aware of the contents hereof and that the matters and facts set forth herein are true and correct to the best of his or her knowledge, information and belief.

SWORN AND SUBSCRIBED TO before me
the day and year first aforesaid.

Darnell Peoples-Scoggins
Signature of Notary

Commonwealth of Pennsylvania - Notary Seal
Darnell Peoples-Scoggins, Notary Public
Allegheny County
My commission expires April 12, 2025
Commission number 1127572
Member, Pennsylvania Association of Notaries

Eric C. Stoltenberg
Signature of Complainant or Representative

FAILURE TO FILE AN ORIGINAL AND THREE (3) COPIES OF THE CHARGE AND ALL ACCOMPANYING EXHIBITS MAY DELAY PROCESSING.

SPECIFICATION OF CHARGES

1. The Complainant is the Allegheny County Police Association (hereinafter "Association"), a labor organization and the exclusive representative of the bargaining unit of police officers employed by the County of Allegheny pursuant to Act 111 of 1968, 43 P.S. §217.1 *et seq*, and the Pennsylvania Labor Relations Act (hereinafter "PLRA") 43 P.S. §211.1 *et seq*.

2. The Respondent is the County of Allegheny (hereinafter "County"), a Municipal Corporation and political subdivision of the Commonwealth, and the public employer of the Complainant's members within the meaning of Act 111 and the PLRA.

3. On September 29, 2021, the County implemented a COVID-19 vaccine mandate for the Association's bargaining unit members. This mandate requires members to show proof of vaccination no later than December 1, 2021, which means proof that the member received the 2nd dose of a two-dose vaccine or proof of having received the single dose of the one-dose vaccine. Members who are vaccinated are required to show proof thereof and those who are not vaccinated are required to become vaccinated and to show proof of same. The County communicated its mandate to the members via email.

4. The County's mandate announced that employees failing to provide proof of vaccination will be subject to termination of employment.

5. The County's mandate did not include any express exceptions to the mandate, such as a bona fide religious objection or an underlying medical condition rendering vaccination a threat to the employee's health.

6. The County's mandate did not address whether the County would make the vaccine available to employees, and if so whether their vaccinations would take place during working hours or non-work hours. The County did not address any other issues related to the vaccines such as whether an employee who becomes disabled after having received a vaccination will be provided work related disability benefits.

7. The imposition of the COVID-19 vaccination mandate upon the Association's members constitutes a mandatory subject of collective bargaining within the meaning of Act 111 and the PLRA, specifically Sections 6(1)(a) and (e).

8. The County did not bargain with the Association prior to implementing the aforementioned vaccination mandate, but acted unilaterally. This unilateral action constitutes an unfair practice in violation of Act 111 and Sections 6(1)(a) and (e) of the PLRA.

9. The County is required to rescind the COVID-19 vaccination mandate unless and until it satisfies its collective bargaining obligation pursuant to Act 111 and the PLRA.

10. The Association respectfully requests that this PLRB declare the unilateral imposition of the new vaccination mandate an unfair labor practice within the meaning of Act 111 and

Sections 6(1)(a) and (e) of the PLRA, direct the County to rescind the mandate and to cease and desist from engaging in such unlawful actions. The Association further requests that the PLRB order the County to make the bargaining unit members whole for any and all losses sustained due to the unlawful action. All other appropriate relief is requested.

FACT SHEET FOR RECIPIENTS AND CAREGIVERS

EMERGENCY USE AUTHORIZATION (EUA) OF THE JANSSEN COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 18 YEARS OF AGE AND OLDER

You are being offered the Janssen COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of receiving the Janssen COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Janssen COVID-19 Vaccine may prevent you from getting COVID-19.

Read this Fact Sheet for information about the Janssen COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Janssen COVID-19 Vaccine.

The Janssen COVID-19 Vaccine is administered as a **single dose**, into the muscle.

The Janssen COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please visit www.janssencovid19vaccine.com.

WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

WHAT IS COVID-19?

COVID-19 is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Common symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

WHAT IS THE JANSSEN COVID-19 VACCINE?

The Janssen COVID-19 Vaccine is an unapproved vaccine that may prevent COVID-19.

The FDA has authorized the emergency use of the Janssen COVID-19 Vaccine to prevent COVID-19 in individuals 18 years of age and older under an Emergency Use Authorization (EUA).

For more information on EUA, see the "**What is an Emergency Use Authorization (EUA)?**" section at the end of this Fact Sheet.

EXHIBIT
C-4

WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE JANSSEN COVID-19 VACCINE?

Tell the vaccination provider about all of your medical conditions, including if you:

- have any allergies,
- have a fever,
- have a bleeding disorder or are on a blood thinner,
- are immunocompromised or are on a medicine that affects your immune system,
- are pregnant or plan to become pregnant,
- are breastfeeding,
- have received another COVID-19 vaccine,
- have ever fainted in association with an injection.

WHO SHOULD GET THE JANSSEN COVID-19 VACCINE?

FDA has authorized the emergency use of the Janssen COVID-19 Vaccine in individuals 18 years of age and older.

WHO SHOULD NOT GET THE JANSSEN COVID-19 VACCINE?

You should not get the Janssen COVID-19 Vaccine if you:

- had a severe allergic reaction to any ingredient of this vaccine.

WHAT ARE THE INGREDIENTS IN THE JANSSEN COVID-19 VACCINE?

The Janssen COVID-19 Vaccine includes the following ingredients: recombinant, replication-incompetent adenovirus type 26 expressing the SARS-CoV-2 spike protein, citric acid monohydrate, trisodium citrate dihydrate, ethanol, 2-hydroxypropyl-β-cyclodextrin (HBCD), polysorbate-80, sodium chloride.

HOW IS THE JANSSEN COVID -19 VACCINE GIVEN?

The Janssen COVID-19 Vaccine will be given to you as an injection into the muscle.

The Janssen COVID-19 Vaccine vaccination schedule is a single dose.

HAS THE JANSSEN COVID-19 VACCINE BEEN USED BEFORE?

The Janssen COVID-19 Vaccine is an unapproved vaccine. In an ongoing clinical trial, 21,895 individuals 18 years of age and older have received the Janssen COVID-19 Vaccine.

WHAT ARE THE BENEFITS OF THE JANSSEN COVID-19 VACCINE?

In an ongoing clinical trial, the Janssen COVID-19 Vaccine has been shown to prevent COVID-19 following a single dose. The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF THE JANSSEN COVID-19 VACCINE?

Side effects that have been reported with the Janssen COVID-19 Vaccine include:

- Injection site reactions: pain, redness of the skin and swelling.
- General side effects: headache, feeling very tired, muscle aches, nausea, and fever.
- Swollen lymph nodes.
- Unusual feeling in the skin (such as tingling or a crawling feeling) (paresthesia), decreased feeling or sensitivity, especially in the skin (hypoesthesia).
- Persistent ringing in the ears (tinnitus).
- Diarrhea, vomiting.

Severe Allergic Reactions

There is a remote chance that the Janssen COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Janssen COVID-19 Vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing,
- Swelling of your face and throat,
- A fast heartbeat,
- A bad rash all over your body,
- Dizziness and weakness.

Blood Clots with Low Levels of Platelets

Blood clots involving blood vessels in the brain, lungs, abdomen, and legs along with low levels of platelets (blood cells that help your body stop bleeding), have occurred in some people who have received the Janssen COVID-19 Vaccine. In people who developed these blood clots and low levels of platelets, symptoms began approximately one to two weeks after vaccination. Reporting of these blood clots and low levels of platelets has been highest in females ages 18 through 49 years. The chance of having this occur is remote. You should seek medical attention right away if you have any of the following symptoms after receiving Janssen COVID-19 Vaccine:

- Shortness of breath,

- Chest pain,
- Leg swelling,
- Persistent abdominal pain,
- Severe or persistent headaches or blurred vision,
- Easy bruising or tiny blood spots under the skin beyond the site of the injection.

These may not be all the possible side effects of the Janssen COVID-19 Vaccine. Serious and unexpected effects may occur. The Janssen COVID-19 Vaccine is still being studied in clinical trials.

Guillain Barré Syndrome

Guillain Barré syndrome (a neurological disorder in which the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis) has occurred in some people who have received the Janssen COVID-19 Vaccine. In most of these people, symptoms began within 42 days following receipt of the Janssen COVID-19 Vaccine. The chance of having this occur is very low. You should seek medical attention right away if you develop any of the following symptoms after receiving the Janssen COVID-19 Vaccine:

- Weakness or tingling sensations, especially in the legs or arms, that's worsening and spreading to other parts of the body.
- Difficulty walking.
- Difficulty with facial movements, including speaking, chewing, or swallowing.
- Double vision or inability to move eyes.
- Difficulty with bladder control or bowel function.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?

If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

Report vaccine side effects to **FDA/CDC Vaccine Adverse Event Reporting System (VAERS).** The VAERS toll-free number is 1-800-822-7967 or report online to https://vaers.hhs.gov/reportevent.html. Please include "Janssen COVID-19 Vaccine EUA" in the first line of box #18 of the report form.

In addition, you can report side effects to Janssen Biotech, Inc. at the contact information provided below.

e-mail	Fax number	Telephone numbers
JNJvaccineAE@its.jnj.com	215-293-9955	US Toll Free: 1-800-565-4008 US Toll: (908) 455-9922

You may also be given an option to enroll in v-safe. V-safe is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. V-safe asks questions that help CDC monitor the safety of COVID-19 vaccines. V-safe also provides live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information on how to sign up, visit: www.cdc.gov/vsafe.

WHAT IF I DECIDE NOT TO GET THE JANSSEN COVID-19 VACCINE?

It is your choice to receive or not receive the Janssen COVID-19 Vaccine. Should you decide not to receive it, it will not change your standard medical care.

ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES JANSSEN COVID-19 VACCINE?

Another choice for preventing COVID-19 is Comirnaty, an FDA-approved COVID-19 vaccine. Other vaccines to prevent COVID-19 may be available under Emergency Use Authorization.

CAN I RECEIVE THE JANSSEN COVID-19 VACCINE WITH OTHER VACCINES?

There is no information on the use of the Janssen COVID-19 Vaccine with other vaccines.

WHAT IF I AM PREGNANT OR BREASTFEEDING?

If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

WILL THE JANSSEN COVID-19 VACCINE GIVE ME COVID-19?

No. The Janssen COVID-19 Vaccine does not contain SARS-CoV-2 and cannot give you COVID-19.

KEEP YOUR VACCINATION CARD

When you receive the Janssen COVID-19 Vaccine, you will get a vaccination card to document the name of the vaccine and date of when you received the vaccine.

ADDITIONAL INFORMATION

If you have questions or to access the most recent Janssen COVID-19 Vaccine Fact Sheets, scan the QR code using your device, visit the website or call the telephone numbers provided below.

QR Code	Fact Sheets Website	Telephone numbers
	www.janssencovid19vaccine.com.	US Toll Free: 1-800-565-4008 US Toll: (908) 455-9922

HOW CAN I LEARN MORE?

- Ask the vaccination provider.
- Visit CDC at https://www.cdc.gov/coronavirus/2019-ncov/index.html.
- Visit FDA at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

Contact your local or state public health department.

WHERE WILL MY VACCINATION INFORMATION BE RECORDED?

The vaccination provider may include your vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. For more information about IISs visit: https://www.cdc.gov/vaccines/programs/iis/about.html.

CAN I BE CHARGED AN ADMINISTRATION FEE FOR RECEIPT OF THE COVID-19 VACCINE?

No. At this time, the provider cannot charge you for a vaccine dose and you cannot be charged an out-of-pocket vaccine administration fee or any other fee if only receiving a COVID-19 vaccination. However, vaccination providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient (private insurance, Medicare, Medicaid, HRSA COVID-19 Uninsured Program for non-insured recipients).

WHERE CAN I REPORT CASES OF SUSPECTED FRAUD?

Individuals becoming aware of any potential violations of the CDC COVID-19 Vaccination Program requirements are encouraged to report them to the Office of the Inspector General, U.S. Department of Health and Human Services, at 1-800-HHS-TIPS or TIPS.HHS.GOV.

WHAT IS THE COUNTERMEASURE INJURY COMPENSATION PROGRAM?

The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses for certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must

be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit www.hrsa.gov/cicp or call 1-855-266-2427.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?

The United States FDA has made the Janssen COVID-19 Vaccine available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

The Janssen COVID-19 Vaccine has not undergone the same type of review as an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used during the COVID-19 pandemic.

The EUA for the Janssen COVID-19 Vaccine is in effect for the duration of the COVID-19 declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).

Manufactured by:
Janssen Biotech, Inc.
a Janssen Pharmaceutical Company of Johnson & Johnson
Horsham, PA 19044, USA

janssen | PHARMACEUTICAL COMPANIES OF Johnson & Johnson

For more information, call US Toll Free: 1-800-565-4008, US Toll: (908) 455-9922 or go to www.janssencovid19vaccine.com

Revised: Aug/27/2021

cp-205985v5

Scan to capture that this Fact Sheet was provided to vaccine recipient for the electronic medical records/immunization information systems.

Barcode Date: 02/2021

FACT SHEET FOR RECIPIENTS AND CAREGIVERS
EMERGENCY USE AUTHORIZATION (EUA) OF THE MODERNA COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 18 YEARS OF AGE AND OLDER

You are being offered the Moderna COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of the Moderna COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Moderna COVID-19 Vaccine is a vaccine and may prevent you from getting COVID-19.

Read this Fact Sheet for information about the Moderna COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Moderna COVID-19 Vaccine.

The Moderna COVID-19 Vaccine is administered as a 2-dose series, 1 month apart, into the muscle.

The Moderna COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please visit www.modernatx.com/covid19vaccine-eua.

WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

WHAT IS COVID-19?
COVID-19 is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

WHAT IS THE MODERNA COVID-19 VACCINE?
The Moderna COVID-19 Vaccine is an unapproved vaccine that may prevent COVID-19.

The FDA has authorized the emergency use of the Moderna COVID-19 Vaccine to prevent COVID-19 in individuals 18 years of age and older under an Emergency Use Authorization (EUA).

For more information on EUA, see the "**What is an Emergency Use Authorization (EUA)?**" section at the end of this Fact Sheet.

WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE MODERNA COVID-19 VACCINE?

Tell your vaccination provider about all of your medical conditions, including if you:

- have any allergies
- have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your immune system
- are pregnant or plan to become pregnant
- are breastfeeding
- have received another COVID-19 vaccine
- have ever fainted in association with an injection

WHO SHOULD GET THE MODERNA COVID-19 VACCINE?

FDA has authorized the emergency use of the Moderna COVID-19 Vaccine in individuals 18 years of age and older.

WHO SHOULD NOT GET THE MODERNA COVID-19 VACCINE?

You should not get the Moderna COVID-19 Vaccine if you:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine

WHAT ARE THE INGREDIENTS IN THE MODERNA COVID-19 VACCINE?

The Moderna COVID-19 Vaccine contains the following ingredients: messenger ribonucleic acid (mRNA), lipids (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate trihydrate, and sucrose.

HOW IS THE MODERNA COVID-19 VACCINE GIVEN?

The Moderna COVID-19 Vaccine will be given to you as an injection into the muscle.

The Moderna COVID-19 Vaccine vaccination series is 2 doses given 1 month apart.

If you receive one dose of the Moderna COVID-19 Vaccine, you should receive a second dose of the same vaccine 1 month later to complete the vaccination series.

If you are immunocompromised, you may receive a third dose of the Moderna COVID-19 Vaccine at least 1 month after the second dose.

HAS THE MODERNA COVID-19 VACCINE BEEN USED BEFORE?

The Moderna COVID-19 Vaccine is an unapproved vaccine. In clinical trials, approximately 15,400 individuals 18 years of age and older have received at least 1 dose of the Moderna COVID-19 Vaccine.

WHAT ARE THE BENEFITS OF THE MODERNA COVID-19 VACCINE?

In an ongoing clinical trial, the Moderna COVID-19 Vaccine has been shown to prevent COVID-19 following 2 doses given 1 month apart. The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF THE MODERNA COVID-19 VACCINE?

There is a remote chance that the Moderna COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Moderna COVID-19 Vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the Moderna COVID-19 Vaccine. In most of these people, symptoms began within a few days following receipt of the second dose of the Moderna COVID-19 Vaccine. The chance of having this occur is very low. You should seek medical attention right away if you have any of the following symptoms after receiving the Moderna COVID-19 Vaccine:

- Chest pain
- Shortness of breath
- Feelings of having a fast-beating, fluttering, or pounding heart

Side effects that have been reported in a clinical trial with the Moderna COVID-19 Vaccine include:

- Injection site reactions: pain, tenderness and swelling of the lymph nodes in the same arm of the injection, swelling (hardness), and redness
- General side effects: fatigue, headache, muscle pain, joint pain, chills, nausea and vomiting, and fever

Side effects that have been reported during post-authorization use of the Moderna COVID-19 Vaccine include:

- Severe allergic reactions
- Myocarditis (inflammation of the heart muscle)
- Pericarditis (inflammation of the lining outside the heart)

These may not be all the possible side effects of the Moderna COVID-19 Vaccine. Serious and unexpected side effects may occur. The Moderna COVID-19 Vaccine is still being studied in clinical trials.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?

If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

Report vaccine side effects to **FDA/CDC Vaccine Adverse Event Reporting System (VAERS)**. The VAERS toll-free number is 1-800-822-7967 or report online to https://vaers.hhs.gov/reportevent.html. Please include "Moderna COVID-19 Vaccine EUA" in the first line of box #18 of the report form.

In addition, you can report side effects to ModernaTX, Inc. at 1-866-MODERNA (1-866-663-3762).

You may also be given an option to enroll in **v-safe. V-safe** is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. **V-safe** asks questions that help CDC monitor the safety of COVID-19 vaccines. **V-safe** also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information on how to sign up, visit: www.cdc.gov/vsafe.

WHAT IF I DECIDE NOT TO GET THE MODERNA COVID-19 VACCINE?
It is your choice to receive or not receive the Moderna COVID-19 Vaccine. Should you decide not to receive it, it will not change your standard medical care.

ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES MODERNA COVID-19 VACCINE?
Another choice for preventing COVID-19 is Comirnaty, an FDA-approved COVID-19 vaccine. Other vaccines to prevent COVID-19 may be available under Emergency Use Authorization.

CAN I RECEIVE THE MODERNA COVID-19 VACCINE WITH OTHER VACCINES?
There is no information on the use of the Moderna COVID-19 Vaccine with other vaccines.

WHAT IF I AM IMMUNOCOMPROMISED?
If you are immunocompromised, you may receive a third dose of the Moderna COVID-19 Vaccine. The third dose may still not provide full immunity to COVID-19 in people who are immunocompromised, and you should continue to maintain physical precautions to help prevent COVID-19. In addition, your close contacts should be vaccinated as appropriate.

WHAT IF I AM PREGNANT OR BREASTFEEDING?
If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

WILL THE MODERNA COVID-19 VACCINE GIVE ME COVID-19?
No. The Moderna COVID-19 Vaccine does not contain SARS-CoV-2 and cannot give you COVID-19.

KEEP YOUR VACCINATION CARD

When you receive your first dose, you will get a vaccination card to show you when to return for your second dose of the Moderna COVID-19 Vaccine. Remember to bring your card when you return.

ADDITIONAL INFORMATION

If you have questions, visit the website or call the telephone number provided below.

To access the most recent Fact Sheets, please scan the QR code provided below.

Moderna COVID-19 Vaccine website	Telephone number
www.modernatx.com/covid19vaccine-eua	1-866-MODERNA (1-866-663-3762)

HOW CAN I LEARN MORE?

- Ask the vaccination provider
- Visit CDC at https://www.cdc.gov/coronavirus/2019-ncov/index.html
- Visit FDA at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization
- Contact your state or local public health department

WHERE WILL MY VACCINATION INFORMATION BE RECORDED?

The vaccination provider may include your vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. This will ensure that you receive the same vaccine when you return for the second dose. For more information about IISs, visit: https://www.cdc.gov/vaccines/programs/iis/about.html.

CAN I BE CHARGED AN ADMINISTRATION FEE FOR RECEIPT OF THE COVID-19 VACCINE?

No. At this time, the provider cannot charge you for a vaccine dose and you cannot be charged an out-of-pocket vaccine administration fee or any other fee if only receiving a COVID-19 vaccination. However, vaccination providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient (private insurance, Medicare, Medicaid, HRSA COVID-19 Uninsured Program for non-insured recipients).

WHERE CAN I REPORT CASES OF SUSPECTED FRAUD?

Individuals becoming aware of any potential violations of the CDC COVID-19 Vaccination Program requirements are encouraged to report them to the Office of the Inspector General, U.S. Department of Health and Human Services, at 1-800-HHS-TIPS or TIPS.HHS.GOV.

WHAT IS THE COUNTERMEASURES INJURY COMPENSATION PROGRAM?
The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit www.hrsa.gov/cicp/ or call 1-855-266-2427.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?
The United States FDA has made the Moderna COVID-19 Vaccine available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

The Moderna COVID-19 Vaccine has not undergone the same type of review as an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and available alternatives. In addition, the FDA decision is based on the totality of the scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used during the COVID-19 pandemic.

The EUA for the Moderna COVID-19 Vaccine is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).

Moderna US, Inc.
Cambridge, MA 02139

Patent(s): www.modernatx.com/patents
Revised: Aug/27/2021

Scan to capture that this Fact Sheet was provided to vaccine recipient for the electronic medical records/immunization information systems.

Barcode Date: 04/2021

VACCINE INFORMATION FACT SHEET FOR RECIPIENTS AND CAREGIVERS ABOUT COMIRNATY (COVID-19 VACCINE, mRNA) AND PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)

You are being offered either COMIRNATY (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2.

This Vaccine Information Fact Sheet for Recipients and Caregivers comprises the Fact Sheet for the authorized Pfizer-BioNTech COVID-19 Vaccine and also includes information about the FDA-licensed vaccine, COMIRNATY (COVID-19 Vaccine, mRNA).

The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the FDA-authorized Pfizer-BioNTech COVID-19 Vaccine under Emergency Use Authorization (EUA) have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series.[1]

COMIRNATY (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine made by Pfizer for BioNTech. It is approved as a 2-dose series for prevention of COVID-19 in individuals 16 years of age and older. It is also authorized under EUA to provide:

- **a two-dose primary series in individuals 12 through 15 years;**
- **a third primary series dose in individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise; and**
- **a single booster dose in individuals:**
  - **65 years of age and older**
  - **18 through 64 years of age at high risk of severe COVID-19**
  - **18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19**

The Pfizer-BioNTech COVID-19 Vaccine has received EUA from FDA to provide:

- **a two-dose primary series in individuals 12 years of age and older;**
- **a third primary series dose for individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise; and**
- **a single booster dose in individuals:**
  - **65 years of age and older**

[1] The licensed vaccine has the same formulation as the EUA-authorized vaccine and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns. The products are legally distinct with certain differences that do not impact safety or effectiveness.

- **18 through 64 years of age at high risk of severe COVID-19**
- **18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19**

This Vaccine Information Fact Sheet contains information to help you understand the risks and benefits of COMIRNATY (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19. Talk to your vaccination provider if you have questions.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please see www.cvdvaccine.com.

WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

WHAT IS COVID-19?

COVID-19 disease is caused by a coronavirus called SARS-CoV-2. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness leading to death. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

WHAT IS COMIRNATY (COVID-19 VACCINE, mRNA) AND HOW IS IT RELATED TO THE PFIZER-BIONTECH COVID-19 VACCINE?

COMIRNATY (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series.[1]

For more information on EUA, see the "**What is an Emergency Use Authorization (EUA)?**" section at the end of this Fact Sheet.

WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE VACCINE?

Tell the vaccination provider about all of your medical conditions, including if you:

- have any allergies
- have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- have a fever

[1] The licensed vaccine has the same formulation as the EUA-authorized vaccine and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns. The products are legally distinct with certain differences that do not impact safety or effectiveness.

- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your immune system
- are pregnant or plan to become pregnant
- are breastfeeding
- have received another COVID-19 vaccine
- have ever fainted in association with an injection

HOW IS THE VACCINE GIVEN?
The vaccine will be given to you as an injection into the muscle.

Primary Series: The vaccine is administered as a 2-dose series, 3 weeks apart. A third dose may be administered at least 4 weeks after the second dose to individuals who are determined to have certain kinds of immunocompromise.

Booster Dose: A single booster dose of the vaccine may be administered to individuals:
- 65 years of age and older
- 18 through 64 years of age at high risk of severe COVID-19
- 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19

The vaccine may not protect everyone.

WHO SHOULD NOT GET THE VACCINE?
You should not get the vaccine if you:
- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine.

WHAT ARE THE INGREDIENTS IN THE VACCINE?
The vaccine includes the following ingredients: mRNA, lipids ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2 [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3-phosphocholine, and cholesterol), potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose.

HAS THE VACCINE BEEN USED BEFORE?
Yes. In clinical trials, approximately 23,000 individuals 12 years of age and older have received at least 1 dose of the vaccine. Data from these clinical trials supported the Emergency Use Authorization of the Pfizer-BioNTech COVID-19 Vaccine and the approval of COMIRNATY (COVID-19 Vaccine, mRNA). Millions of individuals have received the vaccine under EUA since December 11, 2020.

WHAT ARE THE BENEFITS OF THE VACCINE?
The vaccine has been shown to prevent COVID-19.

The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF THE VACCINE?
There is a remote chance that the vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the vaccine. In most of these people, symptoms began within a few days following receipt of the second dose of vaccine. The chance of having this occur is very low. You should seek medical attention right away if you have any of the following symptoms after receiving the vaccine:

- Chest pain
- Shortness of breath
- Feelings of having a fast-beating, fluttering, or pounding heart

Side effects that have been reported with the vaccine include:

- severe allergic reactions
- non-severe allergic reactions such as rash, itching, hives, or swelling of the face
- myocarditis (inflammation of the heart muscle)
- pericarditis (inflammation of the lining outside the heart)
- injection site pain
- tiredness
- headache
- muscle pain
- chills
- joint pain
- fever
- injection site swelling
- injection site redness
- nausea
- feeling unwell
- swollen lymph nodes (lymphadenopathy)
- decreased appetite
- diarrhea

- vomiting
- arm pain
- fainting in association with injection of the vaccine

These may not be all the possible side effects of the vaccine. Serious and unexpected side effects may occur. The possible side effects of the vaccine are still being studied in clinical trials.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?
If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

Report vaccine side effects to FDA/CDC Vaccine Adverse Event Reporting System (VAERS). The VAERS toll-free number is 1-800-822-7967 or report online to https://vaers.hhs.gov/reportevent.html. Please include either "COMIRNATY (COVID-19 Vaccine, mRNA)" or "Pfizer-BioNTech COVID-19 Vaccine EUA", as appropriate, in the first line of box #18 of the report form.

In addition, you can report side effects to Pfizer Inc. at the contact information provided below.

Website	Fax number	Telephone number
www.pfizersafetyreporting.com	1-866-635-8337	1-800-438-1985

You may also be given an option to enroll in v-safe. V-safe is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. V-safe asks questions that help CDC monitor the safety of COVID-19 vaccines. V-safe also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information on how to sign up, visit: www.cdc.gov/vsafe.

WHAT IF I DECIDE NOT TO GET COMIRNATY (COVID-19 VACCINE, mRNA) OR THE PFIZER-BIONTECH COVID-19 VACCINE?
Under the EUA, it is your choice to receive or not receive the vaccine. Should you decide not to receive it, it will not change your standard medical care.

ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES COMIRNATY (COVID-19 VACCINE, mRNA) OR PFIZER-BIONTECH COVID-19 VACCINE?
Other vaccines to prevent COVID-19 may be available under Emergency Use Authorization.

CAN I RECEIVE THE COMIRNATY (COVID-19 VACCINE, mRNA) OR PFIZER-BIONTECH COVID-19 VACCINE AT THE SAME TIME AS OTHER VACCINES?
Data have not yet been submitted to FDA on administration of COMIRNATY (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech COVID-19 Vaccine at the same time with other vaccines. If you are considering receiving COMIRNATY (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech COVID-19 Vaccine with other vaccines, discuss your options with your healthcare provider.

WHAT IF I AM IMMUNOCOMPROMISED?
If you are immunocompromised, you may receive a third dose of the vaccine. The third dose may still not provide full immunity to COVID-19 in people who are immunocompromised, and you should continue to maintain physical precautions to help prevent COVID-19. In addition, your close contacts should be vaccinated as appropriate.

WHAT IF I AM PREGNANT OR BREASTFEEDING?
If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

WILL THE VACCINE GIVE ME COVID-19?
No. The vaccine does not contain SARS-CoV-2 and cannot give you COVID-19.

KEEP YOUR VACCINATION CARD
When you get your first dose, you will get a vaccination card to show you when to return for your next dose(s) of the vaccine. Remember to bring your card when you return.

ADDITIONAL INFORMATION
If you have questions, visit the website or call the telephone number provided below.

To access the most recent Fact Sheets, please scan the QR code provided below.

Global website	Telephone number
www.cvdvaccine.com	1-877-829-2619 (1-877-VAX-CO19)

HOW CAN I LEARN MORE?
- Ask the vaccination provider.
- Visit CDC at https://www.cdc.gov/coronavirus/2019-ncov/index.html.
- Visit FDA at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.
- Contact your local or state public health department.

WHERE WILL MY VACCINATION INFORMATION BE RECORDED?
The vaccination provider may include your vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. This will ensure that you receive the same vaccine when you return for the second dose. For more information about IISs visit: https://www.cdc.gov/vaccines/programs/iis/about.html.

CAN I BE CHARGED AN ADMINISTRATION FEE FOR RECEIPT OF THE COVID-19 VACCINE?
No. At this time, the provider cannot charge you for a vaccine dose and you cannot be charged an out-of-pocket vaccine administration fee or any other fee if only receiving a COVID-19 vaccination. However, vaccination providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient (private insurance, Medicare, Medicaid, Health Resources & Services Administration [HRSA] COVID-19 Uninsured Program for non-insured recipients).

WHERE CAN I REPORT CASES OF SUSPECTED FRAUD?
Individuals becoming aware of any potential violations of the CDC COVID-19 Vaccination Program requirements are encouraged to report them to the Office of the Inspector General, U.S. Department of Health and Human Services, at 1-800-HHS-TIPS or https://TIPS.HHS.GOV.

WHAT IS THE COUNTERMEASURES INJURY COMPENSATION PROGRAM?
The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit www.hrsa.gov/cicp/ or call 1-855-266-2427.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?
An Emergency Use Authorization (EUA) is a mechanism to facilitate the availability and use of medical products, including vaccines, during public health emergencies, such as the current COVID-19 pandemic. An EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

The FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used in the treatment of patients during the COVID-19 pandemic.

This EUA for the Pfizer-BioNTech COVID-19 Vaccine and COMIRNATY will end when the Secretary of HHS determines that the circumstances justifying the EUA no longer

exist or when there is a change in the approval status of the product such that an EUA is no longer needed.

Pfizer

Manufactured by
Pfizer Inc., New York, NY 10017

BIONTECH

Manufactured for
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany

LAB-1451-9.3

Revised: 22 September 2021

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Barcode Date: 08/2021

FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS)

EMERGENCY USE AUTHORIZATION (EUA) OF THE JANSSEN COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, Janssen COVID-19 Vaccine, for active immunization to prevent COVID-19 in individuals 18 years of age and older.

SUMMARY OF INSTRUCTIONS FOR COVID-19 VACCINATION PROVIDERS

Vaccination providers enrolled in the federal COVID-19 Vaccination Program must report all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults, and cases of COVID-19 that result in hospitalization or death following administration of the Janssen COVID-19 Vaccine. See "MANDATORY REQUIREMENTS FOR THE JANSSEN COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION" for reporting requirements.

The Janssen COVID-19 Vaccine is a suspension for intramuscular injection administered as a **single dose** (0.5 mL).

See this Fact Sheet for instructions for preparation and administration. This Fact Sheet may have been updated. For the most recent Fact Sheet, please see www.janssencovid19vaccine.com.

For information on clinical trials that are testing the use of the Janssen COVID-19 Vaccine for active immunization against COVID-19, please see www.clinicaltrials.gov.

DESCRIPTION OF COVID-19

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by the novel coronavirus, SARS-CoV-2, that appeared in late 2019. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have reported a wide range of symptoms, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

DOSAGE AND ADMINISTRATION

The storage and handling information in this Fact Sheet supersedes the storage and handling information on the carton and vial labels.

Storage and Handling

Storage Prior to First Puncture of the Vaccine Vial

Store unpunctured multi-dose vials of the Janssen COVID-19 Vaccine at 2°C to 8°C (36°F to 46°F) and protect from light. Do not store frozen.

Revised: Aug/27/2021

EXHIBIT C-5

Unpunctured vials of Janssen COVID-19 Vaccine may be stored between 9°C to 25°C (47°F to 77°F) for up to 12 hours.

The Janssen COVID-19 Vaccine is initially stored frozen by the manufacturer, then shipped at 2°C to 8°C (36°F to 46°F). If vaccine is still frozen upon receipt, thaw at 2°C to 8°C (36°F to 46°F). If needed immediately, thaw at room temperature (maximally 25°C/77°F). At room temperature (maximally 25°C/77°F), a carton of 10 vials will take approximately 4 hours to thaw, and an individual vial will take approximately 1 hour to thaw. Do not refreeze once thawed.

Storage After First Puncture of the Vaccine Vial

After the first dose has been withdrawn, hold the vial between 2° to 8°C (36° to 46°F) for up to 6 hours or at room temperature (maximally 25°C/77°F) for up to 2 hours. Discard the vial if vaccine is not used within these times.

Dosing and Schedule

The Janssen COVID-19 Vaccine is administered intramuscularly as a **single dose** (0.5 mL).

There are no data available on the use of the Janssen COVID-19 Vaccine to complete a vaccination series initiated with another COVID-19 Vaccine.

Dose Preparation

- The Janssen COVID-19 Vaccine is a colorless to slightly yellow, clear to very opalescent suspension. Visually inspect the Janssen COVID-19 Vaccine vials for particulate matter and discoloration prior to administration. If either of these conditions exists, do not administer the vaccine.
- Before withdrawing each dose of vaccine, carefully mix the contents of the multi-dose vial by swirling gently in an upright position for 10 seconds. **Do not shake**.
- Each dose is 0.5 mL. Each vial contains five doses. Do not pool excess vaccine from multiple vials.
- The Janssen COVID-19 Vaccine does not contain a preservative. Record the date and time of first use on the Janssen COVID-19 Vaccine vial label. After the first dose has been withdrawn, hold the vial between 2° to 8°C (36° to 46°F) for up to 6 hours or at room temperature (maximally 25°C/77°F) for up to 2 hours. Discard if vaccine is not used within these times.

Administration

Visually inspect each dose in the dosing syringe prior to administration. The Janssen COVID-19 Vaccine is a colorless to slightly yellow, clear to very opalescent suspension. During the visual inspection,

- verify the final dosing volume of 0.5 mL.
- confirm there are no particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains particulate matter.

Revised: Aug/27/2021

Administer the Janssen COVID-19 Vaccine intramuscularly.

CONTRAINDICATION

Do not administer the Janssen COVID-19 Vaccine to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Janssen COVID-19 Vaccine *(see Full EUA Prescribing Information)*.

WARNINGS

Management of Acute Allergic Reactions

Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Janssen COVID-19 Vaccine.

Monitor Janssen COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html).

Thrombosis with Thrombocytopenia

Reports of adverse events following use of the Janssen COVID-19 Vaccine under emergency use authorization suggest an increased risk of thrombosis involving the cerebral venous sinuses and other sites (including but not limited to the large blood vessels of the abdomen and the veins of the lower extremities) combined with thrombocytopenia and with onset of symptoms approximately one to two weeks after vaccination. The reporting rate of thrombosis with thrombocytopenia following administration of the Janssen COVID-19 Vaccine has been highest in females ages 18 through 49 years; some cases have been fatal. The clinical course of these events shares features with autoimmune heparin-induced thrombocytopenia. In individuals with suspected thrombosis with thrombocytopenia following administration of the Janssen COVID-19 Vaccine, the use of heparin may be harmful and alternative treatments may be needed. Consultation with hematology specialists is strongly recommended. The American Society of Hematology has published considerations relevant to the diagnosis and treatment of thrombosis with thrombocytopenia following administration of the Janssen COVID-19 Vaccine (*https://www.hematology.org/covid-19/vaccine-induced-immune-thrombotic-thrombocytopenia*). *(see Full EUA Prescribing Information)*.

Guillain-Barré Syndrome

Reports of adverse events following use of the Janssen COVID-19 Vaccine under emergency use authorization suggest an increased risk of Guillain-Barré syndrome during the 42 days following vaccination.

Altered Immunocompetence

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Janssen COVID-19 Vaccine.

Syncope

Syncope (fainting) may occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting.

Limitations of Vaccine Effectiveness

The Janssen COVID-19 Vaccine may not protect all vaccinated individuals.

ADVERSE REACTIONS

Adverse Reactions in Clinical Trials

Adverse reactions reported in a clinical trial following administration of the Janssen COVID-19 Vaccine include injection site pain, headache, fatigue, myalgia, nausea, fever, injection site erythema and injection site swelling. In clinical studies, severe allergic reactions, including anaphylaxis, have been reported following administration of the Janssen COVID-19 Vaccine *(see Full EUA Prescribing Information)*.

Adverse Reactions Identified during Post Authorization Use

Severe allergic reactions (including anaphylaxis), thrombosis with thrombocytopenia, Guillain-Barré syndrome, and capillary leak syndrome have been reported following administration of the Janssen COVID-19 Vaccine during mass vaccination outside of clinical trials.

Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Janssen COVID-19 Vaccine.

USE WITH OTHER VACCINES

There is no information on the co-administration of the Janssen COVID-19 Vaccine with other vaccines.

INFORMATION TO PROVIDE TO VACCINE RECIPIENTS/CAREGIVERS

As the vaccination provider, you must communicate to the recipient or their caregiver, information consistent with the "Fact Sheet for Recipients and Caregivers" (and provide a copy or direct the individual to the website www.janssencovid19vaccine.com to obtain the Fact Sheet) prior to the individual receiving the Janssen COVID-19 Vaccine, including:

- FDA has authorized the emergency use of the Janssen COVID-19 Vaccine, which is not an FDA approved vaccine.
- The recipient or their caregiver has the option to accept or refuse the Janssen COVID-19 Vaccine.
- The significant known and potential risks and benefits of the Janssen COVID-19 Vaccine, and the extent to which such risks and benefits are unknown.
- Information about available alternative vaccines and the risks and benefits of those alternatives.

For information on clinical trials that are testing the use of the Janssen COVID-19 Vaccine to prevent COVID-19, please see www.clinicaltrials.gov.

Provide a vaccination card to the recipient or their caregiver with the name of the vaccine ("Janssen COVID-19 Vaccine") and date of administration to document vaccination.

Provide the v-safe information sheet to vaccine recipients/caregivers and encourage vaccine recipients to participate in v-safe. V-safe is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. V-safe asks questions that help CDC monitor the safety of COVID-19 vaccines. V-safe also provides live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information, visit: www.cdc.gov/vsafe.

MANDATORY REQUIREMENTS FOR JANSSEN COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION

In order to mitigate the risks of using this unapproved product under EUA and to optimize the potential benefit of the Janssen COVID-19 Vaccine, the following items are required. Use of unapproved Janssen COVID-19 Vaccine for active immunization to prevent COVID-19 under this EUA is limited to the following (all requirements must be met):

1. The Janssen COVID-19 Vaccine is authorized for use in individuals 18 years of age and older.

2. The vaccination provider must communicate to the individual receiving the Janssen COVID-19 Vaccine or their caregiver, information consistent with the "Fact Sheet for Recipients and Caregivers" prior to the individual receiving the Janssen COVID-19 Vaccine.

3. The vaccination provider must include vaccination information in the state/local jurisdiction's Immunization Information System (IIS) or other designated system.

4. The vaccination provider is responsible for mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS):

    - vaccine administration errors whether or not associated with an adverse event,
    - serious adverse events* (irrespective of attribution to vaccination),
    - cases of Multisystem Inflammatory Syndrome (MIS) in adults, and
    - cases of COVID-19 that result in hospitalization or death.

    Complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html. For further assistance with reporting to VAERS, call 1-800-822-7967. The reports should include the words "Janssen COVID-19 Vaccine EUA" in the description section of the report.

5. The vaccination provider is responsible for responding to FDA requests for information about vaccine administration errors, adverse events, cases of MIS in adults, and cases of COVID-19 that result in hospitalization or death following administration of the Janssen COVID-19 Vaccine to recipients.

   * Serious adverse events are defined as:
     - Death;
     - A life-threatening adverse event;
     - Inpatient hospitalization or prolongation of existing hospitalization;
     - A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
     - A congenital anomaly/birth defect;
     - An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.

OTHER ADVERSE EVENT REPORTING TO VAERS AND JANSSEN BIOTECH, INC.

Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.

To the extent feasible, report adverse events to Janssen Biotech, Inc. using the contact information below or by providing a copy of the VAERS form to Janssen Biotech, Inc:

e-mail	Fax number	Telephone numbers
JNJvaccineAE@its.jnj.com	215-293-9955	US Toll Free: 1-800-565-4008 US Toll: (908) 455-9922

ADDITIONAL INFORMATION

For general questions or to access the most recent Janssen COVID-19 Vaccine Fact Sheets, scan the QR code using your device, visit www.janssencovid19vaccine.com or call the telephone numbers provided below.

QR Code	Fact Sheets Website	Telephone numbers
	www.janssencovid19vaccine.com.	US Toll Free: 1-800-565-4008 US Toll: 1-908-455-9922

AVAILABLE ALTERNATIVES

Comirnaty (COVID-19 Vaccine, mRNA) is an FDA-approved vaccine to prevent COVID-19 caused by SARS-CoV-2. There may be clinical trials or availability under EUA of other COVID-19 vaccines.

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FEDERAL COVID-19 VACCINATION PROGRAM

This vaccine is being made available for emergency use exclusively through the CDC COVID-19 Vaccination Program (the Vaccination Program). Healthcare providers must enroll as providers in the Vaccination Program and comply with the provider requirements. Vaccination providers may not charge any fee for the vaccine and may not charge the vaccine recipient any out-of-pocket charge for administration. However, vaccination providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient (private insurance, Medicare, Medicaid, HRSA COVID-19 Uninsured Program for non-insured recipients). For information regarding provider requirements and enrollment in the CDC COVID-19 Vaccination Program, see *https://www.cdc.gov/vaccines/covid-19/provider-enrollment.html*.

Individuals becoming aware of any potential violations of the CDC COVID-19 Vaccination Program requirements are encouraged to report them to the Office of the Inspector General, U.S. Department of Health and Human Services, at 1-800-HHS-TIPS or TIPS.HHS.GOV.

AUTHORITY FOR ISSUANCE OF THE EUA

The Secretary of the Department of Health and Human Services (HHS) declared a public health emergency that justifies the emergency use of drugs and biological products during the COVID-19 pandemic. In response, FDA has issued an EUA for the unapproved product, Janssen COVID-19 Vaccine, for active immunization to prevent COVID-19 in individuals 18 years of age and older.

FDA issued this EUA, based on Janssen Biotech, Inc.'s request and submitted data.

Although limited scientific information is available, based on the totality of the scientific evidence available to date, it is reasonable to believe that the Janssen COVID-19 Vaccine may be effective for the prevention of COVID-19 in individuals as specified in the Full EUA Prescribing Information.

This EUA for the Janssen COVID-19 Vaccine will end when the Secretary of HHS determines that the circumstances justifying the EUA no longer exist or when there is a change in the approval status of the product such that an EUA is no longer needed.

For additional information about Emergency Use Authorization visit FDA at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

THE COUNTERMEASURES INJURY COMPENSATION PROGRAM

The Countermeasures Injury Compensation Program (CICP) is a federal program that has been created to help pay for related costs of medical care and other specific expenses to compensate people injured after use of certain medical countermeasures. Medical countermeasures are specific vaccines, medications, devices, or other items used to prevent, diagnose, or treat the public during a public health emergency or a security threat. For more information about CICP, visit www.hrsa.gov/cicp, email cicp@hrsa.gov, or call: 1-855-266-2427.

Revised: Aug/27/2021

Manufactured by:
Janssen Biotech, Inc.
a Janssen Pharmaceutical Company of Johnson & Johnson
Horsham, PA 19044, USA

END SHORT VERSION FACT SHEET
Long Version (Full EUA Prescribing Information) Begins On Next Page

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FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION JANSSEN COVID-19 VACCINE

FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION

1 AUTHORIZED USE

Janssen COVID-19 vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older.

2 DOSAGE AND ADMINISTRATION

For intramuscular injection only.

2.1 Preparation for Administration

- The Janssen COVID-19 Vaccine is a colorless to slightly yellow, clear to very opalescent suspension. Visually inspect the Janssen COVID-19 Vaccine vials for particulate matter and discoloration prior to administration. If either of these conditions exists, do not administer the vaccine.
- Before withdrawing each dose of vaccine, carefully mix the contents of the multi-dose vial by swirling gently in an upright position for 10 seconds. **Do not shake**.
- Each dose is 0.5 mL. Each vial contains five doses. Do not pool excess vaccine from multiple vials.
- The Janssen COVID-19 Vaccine does not contain a preservative. Record the date and time of first use on the Janssen COVID-19 Vaccine vial label. After the first dose has been withdrawn, hold the vial between 2° to 8°C (36° to 46°F) for up to 6 hours or at room temperature (maximally 25°C/77°F) for up to 2 hours. Discard if vaccine is not used within these times.

2.2 Administration

Visually inspect each dose in the dosing syringe prior to administration. The Janssen COVID-19 Vaccine is a colorless to slightly yellow, clear to very opalescent suspension. During the visual inspection,

- verify the final dosing volume of 0.5 mL.
- confirm there are no particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains particulate matter.

Administer the Janssen COVID-19 Vaccine intramuscularly.

2.3 Dosing and Schedule

The Janssen COVID-19 Vaccine is administered intramuscularly as a **single dose** (0.5 mL).

There are no data available on the use of the Janssen COVID-19 Vaccine to complete a vaccination series initiated with another COVID-19 Vaccine.

3 DOSAGE FORMS AND STRENGTHS

Janssen COVID-19 Vaccine is a suspension for intramuscular injection. A single dose is 0.5 mL.

4 CONTRAINDICATIONS

Do not administer the Janssen COVID-19 Vaccine to individuals with a known history of severe allergic reaction (e.g., anaphylaxis) to any component of the Janssen COVID-19 Vaccine *[see Description (13)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Management of Acute Allergic Reactions

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Janssen COVID-19 Vaccine.

Monitor Janssen COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines (*https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html*).

5.2 Thrombosis with Thrombocytopenia

Reports of adverse events following use of the Janssen COVID-19 Vaccine under emergency use authorization suggest an increased risk of thrombosis involving the cerebral venous sinuses and other sites (including but not limited to the large blood vessels of the abdomen and the veins of the lower extremities) combined with thrombocytopenia and with onset of symptoms approximately one to two weeks after vaccination *[see Overall Safety Summary (6.2)]*. The reporting rate of thrombosis with thrombocytopenia following administration of the Janssen COVID-19 Vaccine has been highest in females ages 18 through 49 years; some cases have been fatal. The clinical course of these events shares features with autoimmune heparin-induced thrombocytopenia. Specific risk factors for thrombosis with thrombocytopenia following administration of the Janssen COVID-19 Vaccine and the level of potential excess risk due to vaccination are under investigation. Based on currently available evidence, a causal relationship between thrombosis with thrombocytopenia and the Janssen COVID-19 Vaccine is plausible.

Healthcare professionals should be alert to the signs and symptoms of thrombosis with thrombocytopenia in individuals who receive the Janssen COVID-19 Vaccine. In individuals with suspected thrombosis with thrombocytopenia following administration of the Janssen COVID-19 Vaccine, the use of heparin may be harmful and alternative treatments may be needed. Consultation with hematology specialists is strongly recommended. The American Society of Hematology has published considerations relevant to the diagnosis and treatment of thrombosis with thrombocytopenia following administration of the Janssen COVID-19 Vaccine (*https://www.hematology.org/covid-19/vaccine-induced-immune-thrombotic-thrombocytopenia*).

Recipients of Janssen COVID-19 Vaccine should be instructed to seek immediate medical attention if they develop shortness of breath, chest pain, leg swelling, persistent abdominal pain,

neurological symptoms (including severe or persistent headaches or blurred vision), or petechiae beyond the site of vaccination.

5.3 Guillain-Barré Syndrome

Reports of adverse events following use of the Janssen COVID-19 Vaccine under emergency use authorization suggest an increased risk of Guillain-Barré syndrome during the 42 days following vaccination.

5.4 Syncope

Syncope (fainting) may occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting.

5.5 Altered Immunocompetence

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Janssen COVID-19 Vaccine.

5.6 Limitations of Vaccine Effectiveness

The Janssen COVID-19 Vaccine may not protect all vaccinated individuals.

6 OVERALL SAFETY SUMMARY

It is MANDATORY for vaccination providers to report to the Vaccine Adverse Event Reporting System (VAERS) all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults, and hospitalized or fatal cases of COVID-19 following vaccination with the Janssen COVID-19 Vaccine. To the extent feasible, provide a copy of the VAERS form to Janssen Biotech, Inc. Please see the REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS section for details on reporting to VAERS or Janssen Biotech, Inc.

Adverse Reactions in Clinical Trials

In study COV3001, the most common local solicited adverse reaction (≥10%) reported was injection site pain (48.6%). The most common systemic adverse reactions (≥10%) were headache (38.9%), fatigue (38.2%), myalgia (33.2%), and nausea (14.2%) (see Tables 1 to 4).

Severe allergic reactions, including anaphylaxis, have been reported following administration of the Janssen COVID-19 vaccine.

Adverse Reactions Identified during Post Authorization Use

Severe allergic reactions (including anaphylaxis), thrombosis with thrombocytopenia, Guillain-Barré syndrome, and capillary leak syndrome have been reported following administration of the Janssen COVID-19 Vaccine during mass vaccination outside of clinical trials.

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The safety of the Janssen COVID-19 Vaccine has been assessed in an ongoing Phase 3 Study (COV3001). A total of 43,783 individuals were enrolled in this study, of whom 21,895 adults aged 18 years and older received the Janssen COVID-19 Vaccine [Full Analysis Set (FAS)]. This study is being conducted in the United States (n=19,302), Brazil (n=7,278), South Africa (n=6,576), Colombia (n=4,248), Argentina (n=2,996), Peru (n=1,771), Chile (n=1,133), Mexico (n=479). In this study, 45.0% were female, 54.9% were male, 58.7% were White, 19.4% were Black or African American, 45.3% were Hispanic or Latino, 3.3% were Asian, 9.5% were American Indian/Alaska Native and 0.2% were Native Hawaiian or other Pacific Islander, 5.6% were from multiple racial groups and 1.4% were unknown races (see Table 5). The median age of individuals was 52.0 years (range: 18-100). There were 4,217 (9.6%) individuals who were SARS-CoV-2 seropositive at baseline and who were included in the study. In the United States, 838 of 19,302 (4.3%) individuals were SARS-CoV-2 seropositive. Demographic characteristics were similar among individuals who received the Janssen COVID-19 Vaccine and those who received saline placebo.

The safety subset includes 6,736 individuals (3,356 from the Janssen COVID-19 Vaccine group, 3,380 from the placebo group). The demographic profile in the safety subset was similar in terms of age and gender compared to the FAS. A larger percentage of individuals in the safety subset were White (83.4%) compared to the FAS (58.7%). Geographically, the safety subset was limited to individuals from the United States (51.4%), Brazil (38.5%) and South Africa (10.2%). Fewer individuals in the safety subset compared to the FAS were SARS-CoV-2 seropositive at baseline, 4.5% vs. 9.6%, and had at least one comorbidity 34.1% vs 40.8%.

Safety monitoring in the clinical study consisted of monitoring for: (1) solicited local and systemic reactions occurring in the 7 days following vaccination in a subset of individuals (safety subset), (2) unsolicited adverse events (AEs) occurring in the 28 days following vaccination in the safety subset, (3) medically-attended AEs (MAAEs) occurring in the 6 months following vaccination in the entire study population (FAS), (4) serious AEs (SAEs) and AEs leading to study discontinuation for the duration of the study in the entire study population.

Solicited adverse reactions

Shown below are the frequencies of solicited local adverse reactions (Tables 1 and 2) and systemic adverse reactions (Tables 3 and 4) reported in adults by age group in the ongoing Phase 3 clinical trial (COV3001) in the 7 days following vaccination.

Table 1: Solicited Local Adverse Reactions Reported in the 7 Days Following Vaccination - Individuals 18 to 59 Years of Age

Adverse Reactions	Janssen COVID-19 Vaccine N=2,036 n(%)	Placebo N=2,049 n(%)
Injection Site Pain		
Any	1,193 (58.6)	357 (17.4)
Grade 3[a]	8 (0.4)	0
Injection Site Erythema		
Any (≥25 mm)	184 (9.0)	89 (4.3)
Grade 3[b]	6 (0.3)	2 (0.1)
Injection Site Swelling		
Any (≥25 mm)	142 (7.0)	32 (1.6)
Grade 3[b]	5 (0.2)	2 (0.1)

[a] Grade 3 injection site pain: Defined as incapacitating symptoms; inability to do work, school, or usual activities; use of narcotic pain reliever.

[b] Grade 3 injection site swelling and erythema: Defined as >100 mm.

Table 2: Solicited Local Adverse Reactions Reported in the 7 Days Following Vaccination - Individuals 60 Years of Age and Older

Adverse Reactions	Janssen COVID-19 Vaccine N=1,320 n(%)	Placebo N=1,331 n(%)
Injection Site Pain		
Any	439 (33.3)	207 (15.6)
Grade 3[a]	3 (0.2)	2 (0.2)
Injection Site Erythema		
Any (≥25 mm)	61 (4.6)	42 (3.2)
Grade 3[b]	1 (0.1)	0
Injection Site Swelling		
Any (≥25 mm)	36 (2.7)	21 (1.6)
Grade 3[b]	2 (0.2)	0

[a] Grade 3 injection site pain: Defined as incapacitating symptoms; inability to do work, school, or usual activities; use of narcotic pain reliever.

[b] Grade 3 injection site swelling and erythema: Defined as >100 mm.

Table 3: Solicited Systemic Adverse Reactions Reported in the 7 Days Following Vaccination - Individuals 18 to 59 Years of Age

Adverse Reactions	Janssen COVID-19 Vaccine N=2,036 n(%)	Placebo N=2,049 n(%)
Headache		
Any	905 (44.4)	508 (24.8)
Grade 3[a]	18 (0.9)	5 (0.2)
Fatigue		
Any	891 (43.8)	451 (22.0)
Grade 3[b]	25 (1.2)	4 (0.2)
Myalgia		
Any	796 (39.1)	248 (12.1)
Grade 3[b]	29 (1.4)	1 (<0.1)
Nausea		
Any	315 (15.5)	183 (8.9)
Grade 3[b]	3 (0.1)	3 (0.1)
Fever[c]		
Any	261 (12.8)	14 (0.7)
Grade 3	7 (0.3)	0
Use of antipyretic or pain medication	538 (26.4)	123 (6.0)

[a] Grade 3 headache: Defined as incapacitating symptoms; requires bed rest and/or results in loss of work, school, or cancellation of social activities; use of narcotic pain reliever.

[b] Grade 3 fatigue, myalgia, nausea: Defined as incapacitating symptoms; requires bed rest and/or results in loss of work, school, or cancellation of social activities; use of narcotic pain reliever.

[c] Fever of any grade: Defined as body temperature ≥38°C/100.4°F. Grade 3 fever: Defined as 39.0°C - 40.0°C (102.1°F - 104.0°F).

Table 4: Solicited Systemic Adverse Reactions Reported in the 7 Days Following Vaccination - Individuals 60 Years of Age and Older

Adverse Reactions	Janssen COVID-19 Vaccine N=1,320 n(%)	Placebo N=1,331 n(%)
Headache		
Any	401 (30.4)	294 (22.1)
Grade 3[a]	5 (0.4)	4 (0.3)
Fatigue		
Any	392 (29.7)	277 (20.8)
Grade 3[b]	10 (0.8)	5 (0.4)
Myalgia		
Any	317 (24.0)	182 (13.7)
Grade 3[b]	3 (0.2)	5 (0.4)
Nausea		
Any	162 (12.3)	144 (10.8)
Grade 3[b]	3 (0.2)	3 (0.2)
Fever[c]		
Any	41 (3.1)	6 (0.5)
Grade 3	1 (0.1)	0
Use of antipyretic or pain medication	130 (9.8)	68 (5.1)

[a] Grade 3 headache: Defined as incapacitating symptoms; requires bed rest and/or results in loss of work, school, or cancellation of social activities; use of narcotic pain reliever

[b] Grade 3 fatigue, myalgia, nausea: Defined as incapacitating symptoms; requires bed rest and/or results in loss of work, school, or cancellation of social activities; use of narcotic pain reliever.

[c] Fever of any grade: Defined as body temperature ≥38°C/100.4°F. Grade 3 fever: Defined as 39.0°C - 40.0°C (102.1°F - 104.0°F).

Solicited local and systemic adverse reactions reported following administration of the Janssen COVID-19 Vaccine had a median duration of 1 to 2 days.

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Unsolicited adverse events

Individuals within the safety subset in study COV3001 (N=6,736) were monitored for unsolicited adverse events (AEs) for 28 days following vaccination with 99.9% (N= 6,730) of individuals completing the full 28 days of follow-up. The proportion of individuals who reported one or more unsolicited AEs was similar among those in the Janssen COVID-19 Vaccine group (13.1%) and those in the placebo group (12.0%).

Serious Adverse Events (SAEs) and other events of interest

In study COV3001, up to a cut-off date of January 22, 2021, 54.6% of individuals had follow-up duration of 8 weeks. The median follow-up duration for all individuals was 58 days. SAEs, excluding those related to confirmed COVID-19, were reported by 0.4% (n=83) of individuals who received the Janssen COVID-19 Vaccine (N= 21,895) and 0.4% (n=96) of individuals who received placebo (N= 21,888).

Additional adverse events of interest, including but not limited to allergic, neurologic, inflammatory, vascular, and autoimmune disorders, were analyzed among all adverse events collected through protocol-specified safety monitoring procedures as well as unsolicited reporting.

Urticaria (all non-serious) was reported in five vaccinated individuals and 1 individual who received placebo in the 7 days following vaccination. In addition, an SAE of hypersensitivity, not classified as anaphylaxis, was reported in 1 vaccinated individual with urticaria beginning two days following vaccination and angioedema of the lips with no respiratory distress beginning four days following vaccination. The event was likely related to the vaccine.

An SAE of severe pain in the injected arm, not responsive to analgesics, with immediate onset at time of vaccination, and that was ongoing 74 days following vaccination was reported in an individual who received the Janssen COVID-19 Vaccine. An SAE of severe generalized weakness, fever, and headache, with onset on the day following vaccination and resolution three days following vaccination was reported in an individual who received the Janssen COVID-19 Vaccine. Both SAEs are likely related to the vaccine.

Numerical imbalances, with more events in vaccine than placebo recipients, were observed for the following serious and other adverse events of interest in individuals receiving the vaccine or placebo, respectively:

- Thromboembolic events:
    - Deep vein thrombosis: 6 events (2 serious; 5 within 28 days of vaccination) vs. 2 events (1 serious; 2 within 28 days of vaccination).
    - Pulmonary embolism: 4 events (3 serious; 2 within 28 days of vaccination) vs. 1 event (serious and within 28 days of vaccination).
    - Transverse sinus thrombosis with thrombocytopenia: 1 event (serious, with onset of symptoms 8 days post- vaccination) vs. 0.

- Seizures: 4 events (1 serious; 4 within 28 days of vaccination) vs. 1 event (0 serious and 0 within 28 days following vaccination).
- Tinnitus: 6 events (0 serious; 6 within 28 days of vaccination, including 3 within 2 days of vaccination) vs. 0.

For these events, a causal relationship with the Janssen COVID-19 vaccine could not be determined based on study COV3001. The assessment of causality was confounded by the presence of underlying medical conditions that may have predisposed individuals to these events. However, taking into consideration post-authorization experience, a causal relationship with Janssen COVID-19 Vaccine is plausible for thrombosis with thrombocytopenia *[see Warnings and Precautions (5.2) and Overall Safety Summary (6.2)]*.

There were no additional notable patterns or numerical imbalances between treatment groups for specific categories of serious adverse events (including neurologic, neuro-inflammatory, and cardiovascular events) that would suggest a causal relationship to the Janssen COVID-19 Vaccine.

6.2 Post Authorization Experience

The following adverse reactions have been identified during post-authorization use of the Janssen COVID-19 Vaccine. Because these reactions are reported voluntarily, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure.

Blood and Lymphatic System Disorders: Thrombosis with thrombocytopenia, Lymphadenopathy.

Ear and labyrinth disorders: Tinnitus.

Gastrointestinal disorders: Diarrhea, Vomiting.

Immune System Disorders: Allergic reactions, including anaphylaxis.

Nervous System Disorders: Guillain-Barré syndrome, Syncope, Paresthesia, Hypoesthesia.

Vascular Disorders: Capillary leak syndrome, Thrombosis with thrombocytopenia.

8 REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS

See Overall Safety Summary (Section 6) for additional information.

The vaccination provider enrolled in the federal COVID-19 Vaccination Program is responsible for MANDATORY reporting of the listed events following Janssen COVID-19 Vaccine administration to the Vaccine Adverse Event Reporting System (VAERS):

- Vaccine administration errors whether or not associated with an adverse event,
- Serious adverse events* (irrespective of attribution to vaccination),
- Cases of Multisystem Inflammatory Syndrome (MIS) in adults,

- Cases of COVID-19 that result in hospitalization or death.

  * Serious Adverse Events are defined as:
    - Death;
    - A life-threatening adverse event;
    - Inpatient hospitalization or prolongation of existing hospitalization;
    - A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
    - A congenital anomaly/birth defect;
    - An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.

Instructions for Reporting to VAERS

The vaccination provider enrolled in the federal COVID-19 Vaccination Program should complete and submit a VAERS form to FDA using one of the following methods:

- Complete and submit the report online: https://vaers.hhs.gov/reportevent.html, or
- If you are unable to submit this form electronically, you may fax it to VAERS at 1-877-721-0366. If you need additional help submitting a report you may call the VAERS toll-free information line at 1-800-822-7967 or send an email to info@vaers.org.

IMPORTANT: When reporting adverse events or vaccine administration errors to VAERS, please complete the entire form with detailed information. It is important that the information reported to FDA be as detailed and complete as possible. Information to include:

- Patient demographics, (e.g., patient name, date of birth),
- Pertinent medical history,
- Pertinent details regarding admission and course of illness,
- Concomitant medications,
- Timing of adverse event(s) in relationship to administration of Janssen COVID-19 vaccine,
- Pertinent laboratory and virology information,
- Outcome of the event and any additional follow-up information if it is available at the time of the VAERS report. Subsequent reporting of follow-up information should be completed if additional details become available.

The following steps are highlighted to provide the necessary information for safety tracking:

1. In Box 17, provide information on Janssen COVID-19 Vaccine and any other vaccines administered on the same day; and in Box 22, provide information on any other vaccines received within one month prior.

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2. In Box 18, description of the event:

   a. Write "Janssen COVID-19 Vaccine EUA" as the first line.

   b. Provide a detailed report of vaccine administration error and/or adverse event. It is important to provide detailed information regarding the patient and adverse event/medication error for ongoing safety evaluation of this unapproved vaccine. Please see information to include listed above.

3. Contact information:

   a. In Box 13, provide the name and contact information of the prescribing healthcare provider or institutional designee who is responsible for the report.

   b. In Box 14, provide the name and contact information of the best doctor/healthcare professional to contact about the adverse event.

   c. In Box 15, provide the address of the facility where vaccine was given (NOT the healthcare provider's office address).

Other Reporting Instructions

Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.

To the extent feasible, report adverse events to Janssen Biotech, Inc. using the contact information below or by providing a copy of the VAERS form to Janssen Biotech, Inc:

e-mail	Fax number	Telephone numbers
JNJvaccineAE@its.jnj.com	215-293-9955	US Toll Free: 1-800-565-4008 US Toll: (908) 455-9922

10 DRUG INTERACTIONS

There are no data to assess the concomitant administration of the Janssen COVID-19 Vaccine with other vaccines.

11 USE IN SPECIFIC POPULATIONS

11.1 Pregnancy

Pregnancy Exposure Registry

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Janssen COVID-19 Vaccine during pregnancy. Women who are vaccinated with Janssen COVID-19 Vaccine during pregnancy are encouraged to enroll in the registry by visiting https://c-viper.pregistry.com.

Risk Summary

All Pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Available data on Janssen COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.

In a reproductive developmental toxicity study female rabbits were administered 1 mL of the Janssen COVID-19 Vaccine (a single human dose is 0.5 mL) by intramuscular injection 7 days prior to mating and on Gestation Days 6 and 20 (i.e., one vaccination during early and late gestation, respectively). No vaccine related adverse effects on female fertility, embryo-fetal or postnatal development up to Postnatal Day 28 were observed.

11.2 Lactation

Risk Summary

Data are not available to assess the effects of Janssen COVID-19 Vaccine on the breastfed infant or on milk production/excretion.

11.3 Pediatric Use

Emergency Use Authorization of the Janssen COVID-19 Vaccine does not include use in individuals younger than 18 years of age.

11.4 Geriatric Use

Clinical studies of Janssen COVID-19 Vaccine included individuals 65 years of age and older and their data contributes to the overall assessment of safety and efficacy *[see Overall Safety Summary (6.1) and Clinical Trial Results and Supporting Data for EUA (18)]*. Of the 21,895 individuals who received a single-dose of the Janssen COVID-19 Vaccine in COV3001, 19.5% (n=4,259) were 65 years of age and older and 3.7% (n=809) were 75 years of age and older. No overall differences in safety or efficacy were observed between individuals 65 years of age and older and younger individuals.

13 DESCRIPTION

The Janssen COVID-19 Vaccine is a colorless to slightly yellow, clear to very opalescent sterile suspension for intramuscular injection. It contains no visible particulates. The vaccine consists of a replication-incompetent recombinant adenovirus type 26 (Ad26) vector expressing the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) spike (S) protein in a stabilized conformation.

The Ad26 vector expressing the SARS-CoV-2 S protein is grown in PER.C6 TetR cells, in media containing amino acids and no animal-derived proteins. After propagation, the vaccine is processed through several purification steps, formulated with inactive ingredients and filled into vials.

Each 0.5 mL dose of Janssen COVID-19 Vaccine is formulated to contain 5×10^{10} virus particles (VP) and the following inactive ingredients: citric acid monohydrate (0.14 mg), trisodium citrate dihydrate (2.02 mg), ethanol (2.04 mg), 2-hydroxypropyl-β-cyclodextrin (HBCD) (25.50 mg), polysorbate-80 (0.16 mg), sodium chloride (2.19 mg). Each dose may also contain residual amounts of host cell proteins (≤0.15 mcg) and/or host cell DNA (≤3 ng).

Janssen COVID-19 Vaccine does not contain a preservative.

The vial stoppers are not made with natural rubber latex.

14 CLINICAL PHARMACOLOGY

14.1 Mechanism of Action

The Janssen COVID-19 Vaccine is composed of a recombinant, replication-incompetent human adenovirus type 26 vector that, after entering human cells, expresses the SARS-CoV-2 spike (S) antigen without virus propagation. An immune response elicited to the S antigen protects against COVID-19.

18 CLINICAL TRIAL RESULTS AND SUPPORTING DATA FOR EUA

An ongoing, multicenter, randomized, double-blind, placebo-controlled Phase 3 Study (COV3001) (NCT04505722) is being conducted in the United States, South Africa, Brazil, Chile, Argentina, Colombia, Peru and Mexico to assess the efficacy, safety, and immunogenicity of a single-dose of the Janssen COVID-19 Vaccine for the prevention of COVID-19 in adults aged 18 years and older. Randomization was stratified by age (18-59 years, 60 years and older) and presence or absence of comorbidities associated with an increased risk of progression to severe COVID-19. The study allowed for the inclusion of individuals with stable pre-existing medical conditions, defined as disease not requiring significant change in therapy during the 3 months preceding vaccination, as well as individuals with stable human immunodeficiency virus (HIV) infection.

A total of 44,325 individuals were randomized equally to receive Janssen COVID-19 Vaccine or saline placebo. Individuals are planned to be followed for up to 24 months, for assessments of safety and efficacy against COVID-19.

The primary efficacy analysis population of 39,321 individuals (19,630 in the Janssen COVID-19 Vaccine group and 19,691 in the placebo group) included 38,059 SARSCoV-2 seronegative individuals at baseline and 1,262 individuals with an unknown serostatus. Demographic and baseline characteristics were similar among individuals who received the Janssen COVID-19 Vaccine and those who received placebo (see Table 5).

Table 5: Summary of Demographics and Baseline Characteristics - Primary Efficacy Analysis Population

	Janssen COVID-19 Vaccine (N=19,630) n (%)	Placebo (N=19,691) n (%)
Sex		
Male	10,924 (55.6)	10,910 (55.4)
Female	8,702 (44.3)	8,777 (44.6)
Age (years)		
Mean (SD)	51.1 (15.0)	51.2 (15.0)
Median	52.0	53.0
Min, max	(18; 100)	(18; 94)
Age group		
≥18 to 59 years of age	12,830 (65.4)	12,881 (65.4)
≥60 years of age	6,800 (34.6)	6,810 (34.6)
≥65 years of age	3,984 (20.3)	4,018 (20.4)
≥75 years of age	755 (3.8)	693 (3.5)
Race[a]		
White	12,200 (62.1)	12,216 (62.0)
Black or African American	3,374 (17.2)	3,390 (17.2)
Asian	720 (3.7)	663 (3.4)
American Indian/Alaska Native[b]	1,643 (8.4)	1,628 (8.3)
Native Hawaiian or other Pacific Islander	54 (0.3)	45 (0.2)
Multiple	1,036 (5.3)	1,087 (5.5)
Unknown	262 (1.3)	272 (1.4)
Not reported	341 (1.7)	390 (2.0)
Ethnicity		
Hispanic or Latino	8,793 (44.8)	8,936 (45.4)
Not Hispanic or Latino	10,344 (52.7)	10,259 (52.1)
Unknown	173 (0.9)	162 (0.8)
Not reported	319 (1.6)	333 (1.7)
Region		
Northern America (United States)	9,185 (46.8)	9,171 (46.6)
Latin America	7,967 (40.6)	8,014 (40.7)
Southern Africa (South Africa)	2,478 (12.6)	2,506 (12.7)
Comorbidities[c]		
Yes	7,830 (39.9)	7,867 (40.0)
No	11,800 (60.1)	11,824 (60.0)

[a] Some individuals could be classified in more than one category.

[b] Including 175 individuals in the United States, which represents 1% of the population recruited in the United States.

[c] Number of individuals who have 1 or more comorbidities at baseline that increase the risk of progression to severe/critical COVID-19: Obesity defined as BMI ≥30 kg/m^2 (27.5%), hypertension (10.3%), type 2 diabetes (7.2%), stable/well-controlled HIV infection (2.5%), serious heart conditions (2.4%), asthma (1.3%), and in ≤1% of individuals: cancer, cerebrovascular disease, chronic kidney disease, chronic obstructive pulmonary disease, cystic fibrosis, immunocompromised state (weakened immune system) from blood or organ transplant, liver disease, neurologic conditions, pulmonary fibrosis, sickle cell disease, thalassemia and type 1 diabetes, regardless of age.

Efficacy Against COVID-19

The co-primary endpoints evaluated the first occurrence of moderate to severe/critical COVID-19 with onset of symptoms at least 14 days and at least 28 days after vaccination. Moderate to severe/critical COVID-19 was molecularly confirmed by a central laboratory based on a positive SARS-CoV-2 viral RNA result using a polymerase chain reaction (PCR)-based test.

- Moderate COVID-19 was defined based on the following criteria: the individual must have experienced any one of the following new or worsening signs or symptoms: respiratory rate

≥20 breaths/minute, abnormal saturation of oxygen (SpO2) but still >93% on room air at sea level, clinical or radiologic evidence of pneumonia, radiologic evidence of deep vein thrombosis (DVT), shortness of breath or difficulty breathing OR any two of the following new or worsening signs or symptoms: fever (≥38.0°C or ≥100.4°F), heart rate ≥90 beats/minute, shaking chills or rigors, sore throat, cough, malaise, headache, muscle pain (myalgia), gastrointestinal symptoms, new or changing olfactory or taste disorders, red or bruised appearing feet or toes.

- Severe/critical COVID-19 was defined based on the following criteria: the individual must have experienced any one of the following at any time during the course of observation: clinical signs at rest indicative of severe systemic illness (respiratory rate ≥30 breaths/minute, heart rate ≥125 beats/minute, oxygen saturation (SpO2) ≤93% on room air at sea level, or partial pressure of oxygen/fraction of inspired oxygen (PaO2/FiO2) <300 mmHg), respiratory failure (defined as needing high-flow oxygen, non-invasive ventilation, mechanical ventilation, or extracorporeal membrane oxygenation [ECMO]), evidence of shock (defined as systolic blood pressure <90 mmHg, diastolic blood pressure <60 mmHg, or requiring vasopressors), significant acute renal, hepatic, or neurologic dysfunction, admission to intensive care unit (ICU), death.

Final determination of severe/critical COVID-19 cases were made by an independent adjudication committee.

The median length of follow up for efficacy for individuals in the study was 8 weeks post-vaccination. Vaccine efficacy for the co-primary endpoints against moderate to severe/critical COVID-19 in individuals who were seronegative or who had an unknown serostatus at baseline was 66.9% (95% CI: 59.0; 73.4) at least 14 days after vaccination and 66.1% (95% CI: 55.0; 74.8) at least 28 days after vaccination (see Table 6).

Table 6: **Analyses of Vaccine Efficacy Against Centrally Confirmed Moderate to Severe/Critical COVID-19 – With Onset at Least 14 Days and at Least 28 Days Post-Vaccination - Primary Efficacy Analysis Population**

	Janssen COVID-19 Vaccine N=19,630		Placebo N=19,691		
Subgroup	COVID-19 Cases (n)	Person-Years	COVID-19 Cases (n)	Person-Years	% Vaccine Efficacy (95% CI)
14 days post-vaccination					
All subjects[a]	116	3116.6	348	3096.1	66.9 (59.0; 73.4)
18 to 59 years of age	95	2106.8	260	2095.0	63.7 (53.9; 71.6)
60 years and older	21	1009.8	88	1001.2	76.3 (61.6; 86.0)
28 days post-vaccination					
All subjects[a]	66	3102.0	193	3070.7	66.1 (55.0; 74.8)[b]
18 to 59 years of age	52	2097.6	152	2077.0	66.1 (53.3; 75.8)
60 years and older	14	1004.4	41	993.6	66.2 (36.7; 83.0)

[a] Co-primary endpoint.

[b] The adjusted CI implements type I error control for multiple testing and is presented upon meeting the prespecified testing conditions.

Vaccine efficacy against severe/critical COVID-19 at least 14 days after vaccination was 76.7% (95% CI: 54.6; 89.1) and 85.4% (95% CI: 54.2; 96.9) at least 28 days after vaccination (see Table 7).

Table 7: **Analyses of Vaccine Efficacy: Secondary Endpoints of Centrally Confirmed Severe/Critical COVID-19 – in Adults 18 Years of Age and Older With Onset at Least 14 Days and at Least 28 Days Post-Vaccination – Primary Efficacy Analysis Population**

	Janssen COVID-19 Vaccine N=19,630		Placebo N=19,691		
Subgroup	COVID-19 Cases (n)	Person-Years	COVID-19 Cases (n)	Person-Years	% Vaccine Efficacy (95% CI)
14 days post-vaccination					
Severe/critical	14	3125.1	60	3122.0	76.7 (54.6; 89.1)[a]
28 days post-vaccination					
Severe/critical	5	3106.2	34	3082.6	85.4 (54.2; 96.9)[a]

[a] The adjusted CI implements type I error control for multiple testing and is presented upon meeting the prespecified testing conditions.

Among all COVID-19 cases with onset at least 14 days post vaccination, including cases diagnosed by a positive PCR from a local laboratory and still awaiting confirmation at the central laboratory, there were 2 COVID-19 related hospitalizations in the vaccine group (with none after 28 days) and 29 in the placebo group (with 16 after 28 days).

As of the primary analysis cut-off date of January 22, 2021, there were no COVID-19-related deaths reported in Janssen COVID-19 Vaccine recipients compared to 5 COVID-19-related deaths reported in placebo recipients, who were SARS-CoV-2 PCR negative at baseline.

Janssen COVID-19 Vaccine Efficacy in Countries With Different Circulating SARS-CoV-2 Variants.

Exploratory subgroup analyses of vaccine efficacy against moderate to severe/critical COVID-19 and severe/critical COVID-19 for Brazil, South Africa, and the United States were conducted (see Table 8). For the subgroup analyses, all COVID-19 cases accrued up to the primary efficacy analysis data cutoff date, including cases confirmed by the central laboratory and cases with documented positive SARS-CoV-2 PCR from a local laboratory which are still awaiting confirmation by the central laboratory, were included. The concordance rate observed up to the data cut-off date between the PCR results from the local laboratory and the central laboratory was 90.3%.

Table 8: Summary of Vaccine Efficacy against Moderate to Severe/Critical and Severe/Critical COVID-19 for Countries With >100 Reported Moderate to Severe/Critical Cases

		Severity	
	Onset	Moderate to Severe/Critical Point estimate (95% CI)	Severe/Critical Point estimate (95% CI)
US	at least **14 days** after vaccination	74.4% (65.0; 81.6)	78.0% (33.1; 94.6)
	at least **28 days** after vaccination	72.0% (58.2;81.7)	85.9% (-9.4; 99.7)
Brazil	at least **14 days** after vaccination	66.2% (51.0; 77.1)	81.9% (17.0; 98.1)
	at least **28 days** after vaccination	68.1% (48.8; 80.7)	87.6% (7.8; 99.7)
South Africa	at least **14 days** after vaccination	52.0% (30.3; 67.4)	73.1% (40.0; 89.4)
	at least **28 days** after vaccination	64.0% (41.2; 78.7)	81.7% (46.2; 95.4)

Strain sequencing was conducted on available samples with sufficient viral load from centrally confirmed COVID-19 cases (one sequence per case). As of February 12, 2021, samples from 71.7% of central laboratory confirmed primary analysis cases had been sequenced [United States (73.5%), South Africa (66.9%) and Brazil (69.3%)]. In the United States, 96.4% of strains were identified as the Wuhan-H1 variant D614G; in South Africa, 94.5% of strains were identified as the 20H/501Y.V2 variant (B.1.351 lineage); in Brazil, 69.4% of strains were identified to be a variant of the P.2 lineage and 30.6% of strains were identified as the Wuhan-H1 variant D614G. As of February 12, 2021, SARS-CoV-2 variants from the B1.1.7 or P.1 lineages were not found in any of the sequenced samples.

19 HOW SUPPLIED/STORAGE AND HANDLING

Janssen COVID-19 Vaccine is supplied in a carton of 10 multi-dose vials (NDC 59676-580-15). A maximum of 5 doses can be withdrawn from the multi-dose vial.

The storage and handling information in this Fact Sheet supersedes the storage and handling information on the carton and vial labels.

Storage Prior to First Puncture of the Vaccine Vial

Store unpunctured multi-dose vials of the Janssen COVID-19 Vaccine at 2°C to 8°C (36°F to 46°F) and protect from light. Do not store frozen.

Unpunctured vials of Janssen COVID-19 Vaccine may be stored between 9°C to 25°C (47°F to 77°F) for up to 12 hours.

The Janssen COVID-19 Vaccine is initially stored frozen by the manufacturer, then shipped at 2°C to 8°C (36°F to 46°F). If vaccine is still frozen upon receipt, thaw at 2°C to 8°C (36°F to 46°F). If needed immediately, thaw at room temperature (maximally 25°C/77°F). At room temperature (maximally 25°C/77°F), a carton of 10 vials will take approximately 4 hours to thaw, and an individual vial will take approximately 1 hour to thaw. Do not refreeze once thawed.

Storage After First Puncture of the Vaccine Vial

After the first dose has been withdrawn, hold the vial between 2° to 8°C (36° to 46°F) for up to 6 hours or at room temperature (maximally 25°C/77°F) for up to 2 hours. Discard the vial if vaccine is not used within these times.

20 PATIENT COUNSELING INFORMATION

Advise the recipient or caregiver to read the Fact Sheet for Recipients and Caregivers.

The vaccination provider must include vaccination information in the state/local jurisdiction's Immunization Information System (IIS) or other designated system. Advise recipient or caregiver that more information about IISs can be found at: https://www.cdc.gov/vaccines/programs/iis/about.html.

21 CONTACT INFORMATION

For general questions or to access the most recent Janssen COVID-19 Vaccine Fact Sheets, scan the QR code using your device, visit www.janssencovid19vaccine.com or call the telephone numbers provided below.

QR Code	Fact Sheets Website	Telephone numbers
	www.janssencovid19vaccine.com.	US Toll Free: 1-800-565-4008 US Toll: 1-908-455-9922

This Full EUA Prescribing Information may have been updated. For the most recent Full EUA Prescribing Information, please see www.janssencovid19vaccine.com.

Revised: Aug/27/2021

Manufactured by:
Janssen Biotech, Inc.
a Janssen Pharmaceutical Company of Johnson & Johnson
Horsham, PA 19044, USA

Revised: Aug/27/2021

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FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS)
EMERGENCY USE AUTHORIZATION (EUA) OF THE MODERNA COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, **MODERNA COVID-19 VACCINE**, for active immunization to prevent COVID-19 in individuals 18 years of age and older.

SUMMARY OF INSTRUCTIONS FOR COVID-19 VACCINATION PROVIDERS
Vaccination providers enrolled in the federal COVID-19 Vaccination Program must report all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults, and cases of COVID-19 that result in hospitalization or death following administration of the Moderna COVID-19 Vaccine. See "MANDATORY REQUIREMENTS FOR MODERNA COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION" for reporting requirements.

The Moderna COVID-19 Vaccine is a suspension for intramuscular injection administered as a series of two doses (0.5 mL each) 1 month apart.

See this Fact Sheet for instructions for preparation and administration. This Fact Sheet may have been updated. For the most recent Fact Sheet, please see www.modernatx.com/covid19vaccine-eua.

For information on clinical trials that are testing the use of the Moderna COVID-19 Vaccine for active immunization against COVID-19, please see www.clinicaltrials.gov.

DESCRIPTION OF COVID-19
Coronavirus disease 2019 (COVID-19) is an infectious disease caused by the novel coronavirus, SARS-CoV-2, that appeared in late 2019. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have reported a wide range of symptoms, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle and body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

DOSAGE AND ADMINISTRATION

Storage and Handling
The information in this Fact Sheet supersedes the information on the vial and carton labels.

During storage, minimize exposure to room light.

The Moderna COVID-19 Vaccine multiple-dose vials are stored frozen between -50° to -15°C (-58° to 5°F). Store in the original carton to protect from light.

Do not store on dry ice or below -50°C (-58°F). Use of dry ice may subject vials to temperatures colder than -50°C (-58°F).

Vials may be stored refrigerated between 2° to 8°C (36° to 46°F) for up to 30 days prior to first use.

Vials may be stored between 8° to 25°C (46° to 77°F) for a total of 24 hours.

After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Vials should be discarded 12 hours after the first puncture.

Thawed vials can be handled in room light conditions.

Do not refreeze once thawed.

Transportation of Thawed Vials at 2° to 8°C (35° to 46°F)

If transport at -50° to -15°C (-58° to 5°F) is not feasible, available data support transportation of one or more thawed vials for up to 12 hours at 2° to 8°C (35° to 46°F) when shipped using shipping containers which have been qualified to maintain 2° to 8°C (35° to 46°F) and under routine road and air transport conditions with shaking and vibration minimized. Once thawed and transported at 2° to 8°C (35° to 46°F), vials should not be refrozen and should be stored at 2° to 8°C (35° to 46°F) until use.

Dosing and Schedule
The Moderna COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.5 mL each) 1 month apart.

There are no data available on the interchangeability of the Moderna COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of the Moderna COVID-19 Vaccine should receive a second dose of the Moderna COVID-19 Vaccine to complete the vaccination series.

A third dose of the Moderna COVID-19 Vaccine (0.5 mL) administered at least 28 days following the second dose of this vaccine is authorized for administration to individuals at least 18 years of age who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

Dose Preparation

- The Moderna COVID-19 Vaccine multiple-dose vials contain a frozen suspension that does not contain a preservative and must be thawed prior to administration.
- Remove the required number of vial(s) from storage and thaw each vial before use following the instructions below.

Vial	Thaw in Refrigerator	Thaw at Room Temperature
Maximum 11-Dose Vial (range: 10-11 doses)	Thaw in refrigerated conditions between 2° to 8°C for 2 hours and 30 minutes. Let each vial stand at room temperature for 15 minutes before administering.	Alternatively, thaw at room temperature between 15° to 25°C for 1 hour.
Maximum 15-Dose Vial (range: 13-15 doses)	Thaw in refrigerated conditions between 2° to 8°C for 3 hours. Let each vial stand at room temperature for 15 minutes before administering.	Alternatively, thaw at room temperature between 15° to 25°C for 1 hour and 30 minutes.

- After thawing, do not refreeze.
- Swirl vial gently after thawing and between each withdrawal. **Do not shake.** Do not dilute the vaccine.
- The Moderna COVID-19 Vaccine is a white to off-white suspension. It may contain white or translucent product-related particulates. Visually inspect the Moderna COVID-19 Vaccine vials for other particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.
- The Moderna COVID-19 Vaccine is supplied in two multiple-dose vial presentations:
    - A multiple-dose vial containing a maximum of 11 doses: range 10-11 doses (0.5 mL each).
    - A multiple-dose vial containing a maximum of 15 doses: range 13-15 doses (0.5 mL each).
- Depending on the syringes and needles used for each dose, there may not be sufficient volume to extract more than 10 doses from the maximum of 11 doses vial or more than 13 doses from the maximum of 15 doses vial. Irrespective of the type of syringe and needle:
    - Each dose must contain 0.5 mL of vaccine.
    - If the amount of vaccine remaining in the vial cannot provide a full dose of 0.5 mL, discard the vial and contents. Do not pool excess vaccine from multiple vials.
    - Pierce the stopper at a different site each time.
- After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Record the date and time of first use on the Moderna COVID-19 Vaccine vial label. Discard vial after 12 hours. Do not refreeze.

Administration

Visually inspect each dose of the Moderna COVID-19 Vaccine in the dosing syringe prior to administration. The white to off-white suspension may contain white or translucent product-related particulates. During the visual inspection,

- verify the final dosing volume of 0.5 mL.
- confirm there are no other particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains other particulate matter.

Administer the Moderna COVID-19 Vaccine intramuscularly.

CONTRAINDICATION

Do not administer the Moderna COVID-19 Vaccine to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Moderna COVID-19 Vaccine *(see Full EUA Prescribing Information)*.

WARNINGS

Management of Acute Allergic Reactions

Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Moderna COVID-19 Vaccine.

Monitor Moderna COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention (CDC) guidelines (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html).

Myocarditis and Pericarditis

Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The observed risk is higher among males under 40 years of age than among females and older males. The observed risk is highest in males 18 through 24 years of age. Although some cases required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with conservative management. Information is not yet available about potential long-term sequelae. The CDC has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html).

Syncope

Syncope (fainting) may occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting.

Altered Immunocompetence

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Moderna COVID-19 Vaccine.

Limitations of Vaccine Effectiveness

The Moderna COVID-19 Vaccine may not protect all vaccine recipients.

ADVERSE REACTIONS

Adverse reactions reported in a clinical trial following administration of the Moderna COVID-19 Vaccine include pain at the injection site, fatigue, headache, myalgia, arthralgia, chills, nausea/vomiting, axillary swelling/tenderness, fever, swelling at the injection site, and erythema at the injection site. *(See Full EUA Prescribing Information)*

Severe allergic reactions, including anaphylaxis, have been reported following administration of the Moderna COVID-19 Vaccine during mass vaccination outside of clinical trials.

Myocarditis and pericarditis have been reported following administration of the Moderna COVID-19 Vaccine during mass vaccination outside of clinical trials.

Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Moderna COVID-19 Vaccine.

USE WITH OTHER VACCINES

There is no information on the co-administration of the Moderna COVID-19 Vaccine with other vaccines.

INFORMATION TO PROVIDE TO VACCINE RECIPIENTS/CAREGIVERS

As the vaccination provider, you must communicate to the recipient or their caregiver, information consistent with the "Fact Sheet for Recipients and Caregivers" (and provide a copy or direct the individual to the website www.modernatx.com/covid19vaccine-eua to obtain the Fact Sheet) prior to the individual receiving each dose of the Moderna COVID-19 Vaccine, including:

- FDA has authorized the emergency use of the Moderna COVID-19 Vaccine, which is not an FDA-approved vaccine.
- The recipient or their caregiver has the option to accept or refuse the Moderna COVID-19 Vaccine.
- The significant known and potential risks and benefits of the Moderna COVID-19 Vaccine, and the extent to which such risks and benefits are unknown.
- Information about available alternative vaccines and the risks and benefits of those alternatives.

For information on clinical trials that are evaluating the use of the Moderna COVID-19 Vaccine to prevent COVID-19, please see www.clinicaltrials.gov.

Provide a vaccination card to the recipient or their caregiver with the date when the recipient needs to return for the second dose of Moderna COVID-19 Vaccine.

Provide the **v-safe** information sheet to vaccine recipients/caregivers and encourage vaccine recipients to participate in **v-safe**. **V-safe** is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. **V-safe** asks questions that help CDC monitor the safety of COVID-19 vaccines. **V-safe** also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information, visit: www.cdc.gov/vsafe.

MANDATORY REQUIREMENTS FOR MODERNA COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION

In order to mitigate the risks of using this unapproved product under EUA and to optimize the

potential benefit of the Moderna COVID-19 Vaccine, the following items are required. Use of unapproved Moderna COVID-19 Vaccine for active immunization to prevent COVID-19 under this EUA is limited to the following (all requirements **must** be met):

1. The Moderna COVID-19 Vaccine is authorized for use in individuals 18 years of age and older.

2. The vaccination provider must communicate to the individual receiving the Moderna COVID-19 Vaccine or their caregiver information consistent with the "Fact Sheet for Recipients and Caregivers" prior to the individual receiving the Moderna COVID-19 Vaccine.

3. The vaccination provider must include vaccination information in the state/local jurisdiction's Immunization Information System (IIS) or other designated system.

4. The vaccination provider is responsible for mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS):
   - vaccine administration errors whether or not associated with an adverse event,
   - serious adverse events* (irrespective of attribution to vaccination),
   - cases of Multisystem Inflammatory Syndrome (MIS) in adults, and
   - cases of COVID-19 that result in hospitalization or death.

   Complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html. For further assistance with reporting to VAERS, call 1-800-822-7967. The reports should include the words "Moderna COVID-19 Vaccine EUA" in the description section of the report.

5. The vaccination provider is responsible for responding to FDA requests for information about vaccine administration errors, adverse events, cases of MIS in adults, and cases of COVID-19 that result in hospitalization or death following administration of the Moderna COVID-19 Vaccine to recipients.

   *Serious adverse events are defined as:
   - Death;
   - A life-threatening adverse event;
   - Inpatient hospitalization or prolongation of existing hospitalization;
   - A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
   - A congenital anomaly/birth defect;
   - An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.

OTHER ADVERSE EVENT REPORTING TO VAERS AND MODERNATX, INC.
Vaccination providers may report to VAERS other adverse events that are not required to be

reported using the contact information above.

To the extent feasible, report adverse events to ModernaTX, Inc. using the contact information below or by providing a copy of the VAERS form to ModernaTX, Inc.

Email	Fax number	Telephone number
ModernaPV@modernatx.com	1-866-599-1342	1-866-MODERNA (1-866-663-3762)

ADDITIONAL INFORMATION
For general questions, visit the website or call the telephone number provided below.

To access the most recent Moderna COVID-19 Vaccine Fact Sheets, please scan the QR code or visit the website provided below.

Website	Telephone number
www.modernatx.com/covid19vaccine-eua	1-866-MODERNA (1-866-663-3762)

AVAILABLE ALTERNATIVES
Comirnaty (COVID-19 Vaccine, mRNA) is an FDA-approved vaccine to prevent COVID-19 caused by SARS-CoV-2. There may be clinical trials or availability under EUA of other COVID-19 vaccines.

FEDERAL COVID-19 VACCINATION PROGRAM
This vaccine is being made available for emergency use exclusively through the CDC COVID-19 Vaccination Program (the Vaccination Program). Healthcare providers must enroll as providers in the Vaccination Program and comply with the provider requirements. Vaccination providers may not charge any fee for the vaccine and may not charge the vaccine recipient any out-of-pocket charge for administration. However, vaccination providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient (private insurance, Medicare, Medicaid, HRSA COVID-19 Uninsured Program for non-insured recipients). For information regarding provider requirements and enrollment in the CDC COVID-19 Vaccination Program, see https://www.cdc.gov/vaccines/covid-19/provider-enrollment.html.

Individuals becoming aware of any potential violations of the CDC COVID-19 Vaccination Program requirements are encouraged to report them to the Office of the Inspector General, U.S. Department of Health and Human Services, at 1-800-HHS-TIPS or TIPS.HHS.GOV.

AUTHORITY FOR ISSUANCE OF THE EUA

The Secretary of the Department of Health and Human Services (HHS) has declared a public health emergency that justifies the emergency use of drugs and biological products during the COVID-19 Pandemic. In response, the FDA has issued an EUA for the unapproved product, Moderna COVID-19 Vaccine, for active immunization to prevent COVID-19 in individuals 18 years of age and older.

FDA issued this EUA, based on ModernaTX, Inc.'s request and submitted data.

Although limited scientific information is available, based on the totality of the scientific evidence available to date, it is reasonable to believe that the Moderna COVID-19 Vaccine may be effective for the prevention of COVID-19 in individuals as specified in the *Full EUA Prescribing Information.*

This EUA for the Moderna COVID-19 Vaccine will end when the Secretary of HHS determines that the circumstances justifying the EUA no longer exist or when there is a change in the approval status of the product such that an EUA is no longer needed.

For additional information about Emergency Use Authorization, visit FDA at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

COUNTERMEASURES INJURY COMPENSATION PROGRAM

The Countermeasures Injury Compensation Program (CICP) is a federal program that has been created to help pay for related costs of medical care and other specific expenses to compensate people injured after use of certain medical countermeasures. Medical countermeasures are specific vaccines, medications, devices, or other items used to prevent, diagnose, or treat the public during a public health emergency or a security threat. For more information about CICP regarding the vaccines to prevent COVID-19, visit http://www.hrsa.gov/cicp, email cicp@hrsa.gov, or call: 1-855-266-2427.

Moderna US, Inc.
Cambridge, MA 02139

Patent(s): www.modernatx.com/patents
Revised: Aug/27/2021

END SHORT VERSION FACT SHEET
Long Version (Full EUA Prescribing Information) Begins On Next Page

FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION

MODERNA COVID-19 VACCINE

FULL EUA PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed

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FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION

1 AUTHORIZED USE

Moderna COVID-19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older.

2 DOSAGE AND ADMINISTRATION

For intramuscular injection only.

2.1 Preparation for Administration

- The Moderna COVID-19 Vaccine multiple-dose vials contain a frozen suspension that does not contain a preservative and must be thawed prior to administration.
- Remove the required number of vial(s) from storage and thaw each vial before use following the instructions below.

Vial	Thaw in Refrigerator	Thaw at Room Temperature
Maximum 11-Dose Vial (range: 10-11 doses)	Thaw in refrigerated conditions between 2° to 8°C for 2 hours and 30 minutes. Let each vial stand at room temperature for 15 minutes before administering.	Alternatively, thaw at room temperature between 15° to 25°C for 1 hour.
Maximum 15-Dose Vial (range: 13-15 doses)	Thaw in refrigerated conditions between 2° to 8°C for 3 hours. Let each vial stand at room temperature for 15 minutes before administering.	Alternatively, thaw at room temperature between 15° to 25°C for 1 hour and 30 minutes.

- After thawing, do not refreeze.
- Swirl vial gently after thawing and between each withdrawal. **Do not shake.** Do not dilute the vaccine.
- The Moderna COVID-19 Vaccine is a white to off-white suspension. It may contain white or translucent product-related particulates. Visually inspect the Moderna COVID-19 Vaccine vials for other particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.
- The Moderna COVID-19 Vaccine is supplied in two multiple-dose vial presentations:
  - A multiple-dose vial containing a maximum of 11 doses: range 10-11 doses (0.5 mL each).
  - A multiple-dose vial containing a maximum of 15 doses: range 13-15 doses (0.5 mL each).
- Depending on the syringes and needles used for each dose, there may not be sufficient volume to extract more than 10 doses from the maximum of 11 doses vial or more than 13 doses from the maximum of 15 doses vial. Irrespective of the type of syringe and needle:
  - Each dose must contain 0.5 mL of vaccine.
  - If the amount of vaccine remaining in the vial cannot provide a full dose of 0.5 mL, discard the vial and contents. Do not pool excess vaccine from multiple vials.
  - Pierce the stopper at a different site each time.
- After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Record the date and time of first use on the Moderna COVID-19 Vaccine vial label. Discard vial after 12 hours. Do not refreeze.

2.2 Administration

Visually inspect each dose of the Moderna COVID-19 Vaccine in the dosing syringe prior to administration. The white to off-white suspension may contain white or translucent product-related particulates. During the visual inspection,

- verify the final dosing volume of 0.5 mL.
- confirm there are no other particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains other particulate matter.

Administer the Moderna COVID-19 Vaccine intramuscularly.

2.3 Dosing and Schedule
The Moderna COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.5 mL each) 1 month apart.

There are no data available on the interchangeability of the Moderna COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Moderna COVID-19 Vaccine should receive a second dose of Moderna COVID-19 Vaccine to complete the vaccination series.

A third dose of the Moderna COVID-19 Vaccine (0.5 mL) administered at least 28 days following the second dose of this vaccine is authorized for administration to individuals at least 18 years of age who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

3 DOSAGE FORMS AND STRENGTHS

Moderna COVID-19 Vaccine is a suspension for intramuscular injection. A single dose is 0.5 mL.

4 CONTRAINDICATIONS

Do not administer the Moderna COVID-19 Vaccine to individuals with a known history of severe allergic reaction (e.g., anaphylaxis) to any component of the Moderna COVID-19 Vaccine *[see Description (13)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Management of Acute Allergic Reactions

Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Moderna COVID-19 Vaccine.

Monitor Moderna COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention (CDC) guidelines (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html).

5.2 Myocarditis and Pericarditis

Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The observed risk is higher among males under 40 years of age than among females and older males. The observed risk is highest in males 18 through 24 years of age. Although some cases required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with

conservative management. Information is not yet available about potential long-term sequelae. The CDC has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html).

5.3 Syncope
Syncope (fainting) may occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting.

5.4 Altered Immunocompetence
Immunocompromised persons, including individuals receiving immunosuppressive therapy, may have a diminished response to the Moderna COVID-19 Vaccine.

5.5 Limitations of Vaccine Effectiveness
The Moderna COVID-19 Vaccine may not protect all vaccine recipients.

6 OVERALL SAFETY SUMMARY

It is MANDATORY for vaccination providers to report to the Vaccine Adverse Event Reporting System (VAERS) all vaccine administration errors, all serious adverse events, cases of Multi-inflammatory Syndrome (MIS) in adults, and hospitalized or fatal cases of COVID-19 following vaccination with the Moderna COVID-19 Vaccine. To the extent feasible, provide a copy of the VAERS form to ModernaTX, Inc. Please see the REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS section for details on reporting to VAERS and ModernaTX, Inc.

In clinical studies, the adverse reactions in participants 18 years of age and older were pain at the injection site (92.0%), fatigue (70.0%), headache (64.7%), myalgia (61.5%), arthralgia (46.4%), chills (45.4%), nausea/vomiting (23.0%), axillary swelling/tenderness (19.8%), fever (15.5%), swelling at the injection site (14.7%), and erythema at the injection site (10.0%).

Severe allergic reactions, including anaphylaxis, have been reported following administration of the Moderna COVID-19 Vaccine during mass vaccination outside of clinical trials.

Myocarditis and pericarditis have been reported following administration of the Moderna COVID-19 Vaccine during mass vaccination outside of clinical trials.

6.1 Clinical Trials Experience
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared with rates in the clinical trials of another vaccine and may not reflect the rates observed in practice.

Overall, 15,419 participants aged 18 years and older received at least one dose of Moderna COVID-19 Vaccine in three clinical trials (NCT04283461, NCT04405076, and NCT04470427).

The safety of Moderna COVID-19 Vaccine was evaluated in an ongoing Phase 3 randomized, placebo-controlled, observer-blind clinical trial conducted in the United States involving 30,351 participants 18 years of age and older who received at least one dose of Moderna COVID-19 Vaccine (n=15,185) or placebo (n=15,166) (NCT04470427). At the time of vaccination, the mean age of the population was 52 years (range 18-95); 22,831 (75.2%) of participants were 18 to 64 years of age and 7,520 (24.8%) of participants were 65 years of age and older. Overall, 52.7% were male, 47.3% were female, 20.5% were Hispanic or Latino, 79.2% were White, 10.2% were African American, 4.6% were Asian, 0.8% were American Indian or Alaska Native, 0.2% were Native Hawaiian or Pacific Islander, 2.1% were other races, and 2.1% were Multiracial. Demographic characteristics were similar among participants who received Moderna COVID-19 Vaccine and those who received placebo.

Solicited Adverse Reactions

Data on solicited local and systemic adverse reactions and use of antipyretic medication were collected in an electronic diary for 7 days following each injection (i.e., day of vaccination and the next 6 days) among participants receiving Moderna COVID-19 Vaccine (n=15,179) and participants receiving placebo (n=15,163) with at least 1 documented dose. Solicited adverse reactions were reported more frequently among vaccine participants than placebo participants.

The reported number and percentage of the solicited local and systemic adverse reactions by age group and dose are presented in Table 1 and Table 2, respectively.

Table 1: Number and Percentage of Participants With Solicited Local and Systemic Adverse Reactions Within 7 Days* After Each Dose in Participants 18-64 Years (Solicited Safety Set, Dose 1 and Dose 2)

	Moderna COVID-19 Vaccine		Placebo[a]	
	Dose 1 (N=11,406) n (%)	Dose 2 (N=10,985) n (%)	Dose 1 (N=11,407) n (%)	Dose 2 (N=10,918) n (%)
Local Adverse Reactions				
Pain	9,908 (86.9)	9,873 (89.9)	2,177 (19.1)	2,040 (18.7)
Pain, Grade 3[b]	366 (3.2)	506 (4.6)	23 (0.2)	22 (0.2)
Axillary swelling/tenderness	1,322 (11.6)	1,775 (16.2)	567 (5.0)	470 (4.3)
Axillary swelling/tenderness, Grade 3[b]	37 (0.3)	46 (0.4)	13 (0.1)	11 (0.1)
Swelling (hardness) ≥25 mm	767 (6.7)	1,389 (12.6)	34 (0.3)	36 (0.3)
Swelling (hardness), Grade 3[c]	62 (0.5)	182 (1.7)	3 (<0.1)	4 (<0.1)
Erythema (redness) ≥25 mm	344 (3.0)	982 (8.9)	47 (0.4)	43 (0.4)

	Moderna COVID-19 Vaccine		Placebo[a]	
	Dose 1 (N=11,406) n (%)	**Dose 2** (N=10,985) n (%)	**Dose 1** (N=11,407) n (%)	**Dose 2** (N=10,918) n (%)
Erythema (redness), Grade 3[c]	34 (0.3)	210 (1.9)	11 (<0.1)	12 (0.1)
Systemic Adverse Reactions				
Fatigue	4,384 (38.4)	7,430 (67.6)	3,282 (28.8)	2,687 (24.6)
Fatigue, Grade 3[d]	120 (1.1)	1,174 (10.7)	83 (0.7)	86 (0.8)
Fatigue, Grade 4[e]	1 (<0.1)	0 (0)	0 (0)	0 (0)
Headache	4,030 (35.3)	6,898 (62.8)	3,304 (29.0)	2,760 (25.3)
Headache, Grade 3[f]	219 (1.9)	553 (5.0)	162 (1.4)	129 (1.2)
Myalgia	2,699 (23.7)	6,769 (61.6)	1,628 (14.3)	1,411 (12.9)
Myalgia, Grade 3[d]	73 (0.6)	1,113 (10.1)	38 (0.3)	42 (0.4)
Arthralgia	1,893 (16.6)	4,993 (45.5)	1,327 (11.6)	1,172 (10.7)
Arthralgia, Grade 3[d]	47 (0.4)	647 (5.9)	29 (0.3)	37 (0.3)
Arthralgia, Grade 4[e]	1 (<0.1)	0 (0)	0 (0)	0 (0)
Chills	1,051 (9.2)	5,341 (48.6)	730 (6.4)	658 (6.0)
Chills, Grade 3[g]	17 (0.1)	164 (1.5)	8 (<0.1)	15 (0.1)
Nausea/vomiting	1,068 (9.4)	2,348 (21.4)	908 (8.0)	801 (7.3)
Nausea/vomiting, Grade 3[h]	6 (<0.1)	10 (<0.1)	8 (<0.1)	8 (<0.1)
Fever	105 (0.9)	1,908 (17.4)	37 (0.3)	39 (0.4)
Fever, Grade 3[i]	10 (<0.1)	184 (1.7)	1 (<0.1)	2 (<0.1)
Fever, Grade 4[j]	4 (<0.1)	12 (0.1)	4 (<0.1)	2 (<0.1)
Use of antipyretic or pain medication	2,656 (23.3)	6,292 (57.3)	1,523 (13.4)	1,248 (11.4)

* 7 days included day of vaccination and the subsequent 6 days. Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary).

[a] Placebo was a saline solution.

[b] Grade 3 pain and axillary swelling/tenderness: Defined as any use of prescription pain reliever; prevents daily activity.

[c] Grade 3 swelling and erythema: Defined as >100 mm / >10 cm.

[d] Grade 3 fatigue, myalgia, arthralgia: Defined as significant; prevents daily activity.

[e] Grade 4 fatigue, arthralgia: Defined as requires emergency room visit or hospitalization.

[f] Grade 3 headache: Defined as significant; any use of prescription pain reliever or prevents daily activity.
[g] Grade 3 chills: Defined as prevents daily activity and requires medical intervention.
[h] Grade 3 nausea/vomiting: Defined as prevents daily activity, requires outpatient intravenous hydration.
[i] Grade 3 fever: Defined as ≥39.0° – ≤40.0°C / ≥102.1° – ≤104.0°F.
[j] Grade 4 fever: Defined as >40.0°C / >104.0°F.

Table 2: Number and Percentage of Participants With Solicited Local and Systemic Adverse Reactions Within 7 Days* After Each Dose in Participants 65 Years and Older (Solicited Safety Set, Dose 1 and Dose 2)

	Moderna COVID-19 Vaccine		Placebo[a]	
	Dose 1 (N=3,762) n (%)	Dose 2 (N=3,692) n (%)	Dose 1 (N=3,748) n (%)	Dose 2 (N=3,648) n (%)
Local Adverse Reactions				
Pain	2,782 (74.0)	3,070 (83.2)	481 (12.8)	437 (12.0)
Pain, Grade 3[b]	50 (1.3)	98 (2.7)	32 (0.9)	18 (0.5)
Axillary swelling/tenderness	231 (6.1)	315 (8.5)	155 (4.1)	97 (2.7)
Axillary swelling/tenderness, Grade 3[b]	12 (0.3)	21 (0.6)	14 (0.4)	8 (0.2)
Swelling (hardness) ≥25 mm	165 (4.4)	400 (10.8)	18 (0.5)	13 (0.4)
Swelling (hardness), Grade 3[c]	20 (0.5)	72 (2.0)	3 (<0.1)	7 (0.2)
Erythema (redness) ≥25 mm	86 (2.3)	275 (7.5)	20 (0.5)	13 (0.4)
Erythema (redness), Grade 3[c]	8 (0.2)	77 (2.1)	2 (<0.1)	3 (<0.1)
Systemic Adverse Reactions				
Fatigue	1,251 (33.3)	2,152 (58.3)	851 (22.7)	716 (19.6)
Fatigue, Grade 3[d]	30 (0.8)	254 (6.9)	22 (0.6)	20 (0.5)
Headache	921 (24.5)	1,704 (46.2)	723 (19.3)	650 (17.8)
Headache, Grade 3[e]	52 (1.4)	106 (2.9)	34 (0.9)	33 (0.9)
Myalgia	742 (19.7)	1,739 (47.1)	443 (11.8)	398 (10.9)
Myalgia, Grade 3[d]	17 (0.5)	205 (5.6)	9 (0.2)	10 (0.3)
Arthralgia	618 (16.4)	1,291 (35.0)	456 (12.2)	397 (10.9)
Arthralgia, Grade 3[d]	13 (0.3)	123 (3.3)	8 (0.2)	7 (0.2)

	Moderna COVID-19 Vaccine		Placebo[a]	
	Dose 1 (N=3,762) n (%)	**Dose 2** (N=3,692) n (%)	**Dose 1** (N=3,748) n (%)	**Dose 2** (N=3,648) n (%)
Chills	202 (5.4)	1,141 (30.9)	148 (4.0)	151 (4.1)
Chills, Grade 3[f]	7 (0.2)	27 (0.7)	6 (0.2)	2 (<0.1)
Nausea/vomiting	194 (5.2)	437 (11.8)	166 (4.4)	133 (3.6)
Nausea/vomiting, Grade 3[g]	4 (0.1)	10 (0.3)	4 (0.1)	3 (<0.1)
Nausea/vomiting, Grade 4[h]	0 (0)	1 (<0.1)	0 (0)	0 (0)
Fever	10 (0.3)	370 (10.0)	7 (0.2)	4 (0.1)
Fever, Grade 3[i]	1 (<0.1)	18 (0.5)	1 (<0.1)	0 (0)
Fever, Grade 4[j]	0 (0)	1 (<0.1)	2 (<0.1)	1 (<0.1)
Use of antipyretic or pain medication	673 (17.9)	1,546 (41.9)	477 (12.7)	329 (9.0)

* 7 days included day of vaccination and the subsequent 6 days. Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary).
[a] Placebo was a saline solution.
[b] Grade 3 pain and axillary swelling/tenderness: Defined as any use of prescription pain reliever; prevents daily activity.
[c] Grade 3 swelling and erythema: Defined as >100 mm / >10 cm.
[d] Grade 3 fatigue, myalgia, arthralgia: Defined as significant; prevents daily activity.
[e] Grade 3 headache: Defined as significant; any use of prescription pain reliever or prevents daily activity.
[f] Grade 3 chills: Defined as prevents daily activity and requires medical intervention.
[g] Grade 3 Nausea/vomiting: Defined as prevents daily activity, requires outpatient intravenous hydration.
[h] Grade 4 Nausea/vomiting: Defined as requires emergency room visit or hospitalization for hypotensive shock.
[i] Grade 3 fever: Defined as ≥39.0° – ≤40.0°C / ≥102.1° – ≤104.0°F.
[j] Grade 4 fever: Defined as >40.0°C / >104.0°F.

Solicited local and systemic adverse reactions reported following administration of Moderna COVID-19 Vaccine had a median duration of 1 to 3 days.

Grade 3 solicited local adverse reactions were more frequently reported after Dose 2 than after Dose 1. Solicited systemic adverse reactions were more frequently reported by vaccine recipients after Dose 2 than after Dose 1.

Unsolicited Adverse Events

Participants were monitored for unsolicited adverse events for up to 28 days following each dose and follow-up is ongoing. Serious adverse events and medically attended adverse events will be recorded for the entire study duration of 2 years. As of November 25, 2020, among participants who had received at least 1 dose of vaccine or placebo (vaccine=15,185, placebo=15,166), unsolicited adverse events that occurred within 28 days following each vaccination were reported

by 23.9% of participants (n=3,632) who received Moderna COVID-19 Vaccine and 21.6% of participants (n=3,277) who received placebo. In these analyses, 87.9% of study participants had at least 28 days of follow-up after Dose 2.

Lymphadenopathy-related events that were not necessarily captured in the 7-day e-diary were reported by 1.1% of vaccine recipients and 0.6% of placebo recipients. These events included lymphadenopathy, lymphadenitis, lymph node pain, vaccination-site lymphadenopathy, injection-site lymphadenopathy, and axillary mass, which were plausibly related to vaccination. This imbalance is consistent with the imbalance observed for solicited axillary swelling/tenderness in the injected arm.

Hypersensitivity adverse events were reported in 1.5% of vaccine recipients and 1.1% of placebo recipients. Hypersensitivity events in the vaccine group included injection site rash and injection site urticaria, which are likely related to vaccination. Delayed injection site reactions that began >7 days after vaccination were reported in 1.2% of vaccine recipients and 0.4% of placebo recipients. Delayed injection site reactions included pain, erythema, and swelling and are likely related to vaccination.

Throughout the same period, there were three reports of Bell's palsy in the Moderna COVID-19 Vaccine group (one of which was a serious adverse event), which occurred 22, 28, and 32 days after vaccination, and one in the placebo group which occurred 17 days after vaccination. Currently available information on Bell's palsy is insufficient to determine a causal relationship with the vaccine.

There were no other notable patterns or numerical imbalances between treatment groups for specific categories of adverse events (including other neurologic, neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to Moderna COVID-19 Vaccine.

In 60 individuals who had undergone various solid organ transplant procedures (heart, kidney, kidney-pancreas, liver, lung, pancreas) a median of 3.57 years previously (range 1.99-6.75 years) who received a third vaccine dose, the adverse event profile was similar to that after the second dose and no Grade 3 or Grade 4 events were reported.

Serious Adverse Events

As of November 25, 2020, serious adverse events were reported by 1.0% (n=147) of participants who received Moderna COVID-19 Vaccine and 1.0% (n=153) of participants who received placebo, one of which was the case of Bell's palsy which occurred 32 days following receipt of vaccine.

In these analyses, 87.9% of study participants had at least 28 days of follow-up after Dose 2, and the median follow-up time for all participants was 9 weeks after Dose 2.

There were two serious adverse events of facial swelling in vaccine recipients with a history of injection of dermatological fillers. The onset of swelling was reported 1 and 2 days, respectively, after vaccination and was likely related to vaccination.

There was one serious adverse event of intractable nausea and vomiting in a participant with prior history of severe headache and nausea requiring hospitalization. This event occurred 1 day after vaccination and was likely related to vaccination.

There were no other notable patterns or imbalances between treatment groups for specific categories of serious adverse events (including neurologic, neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to Moderna COVID-19 Vaccine.

6.2 Post-Authorization Experience

The following adverse reactions have been identified during post-authorization use of the Moderna COVID-19 Vaccine. Because these reactions are reported voluntarily, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure.

Cardiac Disorders: myocarditis, pericarditis
Immune System Disorders: anaphylaxis
Nervous System Disorders: syncope

8 REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS

See Overall Safety Summary (Section 6) for additional information.

The vaccination provider enrolled in the federal COVID-19 Vaccination Program is responsible for the MANDATORY reporting of the listed events following Moderna COVID-19 Vaccine to the Vaccine Adverse Event Reporting System (VAERS)

- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events* (irrespective of attribution to vaccination)
- Cases of multisystem inflammatory syndrome (MIS) in adults
- Cases of COVID-19 that results in hospitalization or death

*Serious Adverse Events are defined as:

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect;
- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.

Instructions for Reporting to VAERS

The vaccination provider enrolled in the federal COVID-19 Vaccination Program should complete and submit a VAERS form to FDA using one of the following methods:

- Complete and submit the report online: https://vaers.hhs.gov/reportevent.html, or
- If you are unable to submit this form electronically, you may fax it to VAERS at 1-877-721-0366. If you need additional help submitting a report, you may call the VAERS toll-free information line at 1-800-822-7967 or send an email to info@vaers.org.

IMPORTANT: When reporting adverse events or vaccine administration errors to VAERS, please complete the entire form with detailed information. It is important that the information reported to FDA be as detailed and complete as possible. Information to include:

- Patient demographics (e.g., patient name, date of birth)
- Pertinent medical history
- Pertinent details regarding admission and course of illness
- Concomitant medications
- Timing of adverse event(s) in relationship to administration of Moderna COVID-19 Vaccine
- Pertinent laboratory and virology information
- Outcome of the event and any additional follow-up information if it is available at the time of the VAERS report. Subsequent reporting of follow-up information should be completed if additional details become available.

The following steps are highlighted to provide the necessary information for safety tracking:

1. In Box 17, provide information on Moderna COVID-19 Vaccine and any other vaccines administered on the same day; and in Box 22, provide information on any other vaccines received within one month prior.
2. In Box 18, description of the event:
    a. Write "Moderna COVID-19 Vaccine EUA" as the first line
    b. Provide a detailed report of vaccine administration error and/or adverse event. It is important to provide detailed information regarding the patient and adverse event/medication error for ongoing safety evaluation of this unapproved vaccine. Please see information to include listed above.
3. Contact information:
    a. In Box 13, provide the name and contact information of the prescribing healthcare provider or institutional designee who is responsible for the report.
    b. In Box 14, provide the name and contact information of the best doctor/healthcare professional to contact about the adverse event.
    c. In Box 15, provide the address of the facility where vaccine was given (NOT the healthcare provider's office address).

Other Reporting Instructions

Vaccination providers may report to VAERS other adverse events that are not required to be

reported using the contact information above.

To the extent feasible, report adverse events to ModernaTX, Inc. using the contact information below or by providing a copy of the VAERS form to ModernaTX, Inc.

Email	Fax number	Telephone number
ModernaPV@modernatx.com	1-866-599-1342	1-866-MODERNA (1-866-663-3762)

10 DRUG INTERACTIONS

There are no data to assess the concomitant administration of the Moderna COVID-19 Vaccine with other vaccines.

11 USE IN SPECIFIC POPULATIONS

11.1 Pregnancy

Pregnancy Exposure Registry

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Moderna COVID-19 Vaccine during pregnancy. Women who are vaccinated with Moderna COVID-19 Vaccine during pregnancy are encouraged to enroll in the registry by calling 1-866-MODERNA (1-866-663-3762).

Risk Summary

All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively. Available data on Moderna COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.

In a developmental toxicity study, 0.2 mL of a vaccine formulation containing the same quantity of nucleoside-modified messenger ribonucleic acid (mRNA) (100 mcg) and other ingredients included in a single human dose of Moderna COVID-19 Vaccine was administered to female rats by the intramuscular route on four occasions: 28 and 14 days prior to mating, and on gestation days 1 and 13. No vaccine-related adverse effects on female fertility, fetal development, or postnatal development were reported in the study.

11.2 Lactation

Risk Summary

Data are not available to assess the effects of Moderna COVID-19 Vaccine on the breastfed

infant or on milk production/excretion.

11.3 Pediatric Use

Safety and effectiveness have not been assessed in persons less than 18 years of age. Emergency Use Authorization of Moderna COVID-19 Vaccine does not include use in individuals younger than 18 years of age.

11.4 Geriatric Use

Clinical studies of Moderna COVID-19 Vaccine included participants 65 years of age and older receiving vaccine or placebo, and their data contribute to the overall assessment of safety and efficacy. In an ongoing Phase 3 clinical study, 24.8% (n=7,520) of participants were 65 years of age and older and 4.6% (n=1,399) of participants were 75 years of age and older. Vaccine efficacy in participants 65 years of age and older was 86.4% (95% CI 61.4, 95.2) compared to 95.6% (95% CI 90.6, 97.9) in participants 18 to <65 years of age *[see Clinical Trial Results and Supporting Data for EUA (18)]*. Overall, there were no notable differences in the safety profiles observed in participants 65 years of age and older and younger participants *[see Overall Safety Summary (6.1)]*.

11.5 Use in Immunocompromised

Safety and effectiveness of a third dose of the Moderna COVID-19 Vaccine have been tested in persons that received solid organ transplants. The administration of third vaccine doses appears to be only moderately effective in increasing antibody titers, so patients should be counselled to maintain physical precautions to help prevent COVID-19. In addition, close contacts of immunocompromised persons should be vaccinated as appropriate for their health status.

13 DESCRIPTION

Moderna COVID-19 Vaccine is provided as a white to off-white suspension for intramuscular injection. Each 0.5 mL dose of Moderna COVID-19 Vaccine contains 100 mcg of nucleoside-modified messenger RNA (mRNA) encoding the pre-fusion stabilized Spike glycoprotein (S) of SARS-CoV-2 virus.

Each dose of the Moderna COVID-19 Vaccine contains the following ingredients: a total lipid content of 1.93 mg (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), 0.31 mg tromethamine, 1.18 mg tromethamine hydrochloride, 0.043 mg acetic acid, 0.20 mg sodium acetate trihydrate, and 43.5 mg sucrose.

Moderna COVID-19 Vaccine does not contain a preservative.

The vial stoppers are not made with natural rubber latex.

14 CLINICAL PHARMACOLOGY

14.1 Mechanism of Action

The nucleoside-modified mRNA in the Moderna COVID-19 Vaccine is formulated in lipid particles, which enable delivery of the nucleoside-modified mRNA into host cells to allow expression of the SARS-CoV-2 S antigen. The vaccine elicits an immune response to the S antigen, which protects against COVID-19.

18 CLINICAL TRIAL RESULTS AND SUPPORTING DATA FOR EUA

A Phase 3 randomized, placebo-controlled, observer-blind clinical trial to evaluate the efficacy, safety, and immunogenicity of the Moderna COVID-19 Vaccine in participants 18 years of age and older is ongoing in the United States (NCT04470427). Randomization was stratified by age and health risk: 18 to <65 years of age without comorbidities (not at risk for progression to severe COVID-19), 18 to <65 years of age with comorbidities (at risk for progression to severe COVID-19), and 65 years of age and older with or without comorbidities. Participants who were immunocompromised and those with a known history of SARS-CoV-2 infection were excluded from the study. Participants with no known history of SARS-CoV-2 infection but with positive laboratory results indicative of infection at study entry were included. The study allowed for the inclusion of participants with stable pre-existing medical conditions, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 3 months before enrollment, as well as participants with stable human immunodeficiency virus (HIV) infection. A total of 30,420 participants were randomized equally to receive 2 doses of the Moderna COVID-19 Vaccine or saline placebo 1 month apart. Participants will be followed for efficacy and safety until 24 months after the second dose.

The primary efficacy analysis population (referred to as the Per-Protocol Set) included 28,207 participants who received two doses (at 0 and 1 month) of either Moderna COVID-19 Vaccine (n=14,134) or placebo (n=14,073), and had a negative baseline SARS-CoV-2 status. In the Per-Protocol Set, 47.4% were female, 19.7% were Hispanic or Latino; 79.5% were White, 9.7% were African American, 4.6% were Asian, and 2.1% other races. The median age of participants was 53 years (range 18-95) and 25.3% of participants were 65 years of age and older. Of the study participants in the Per-Protocol Set, 18.5% were at increased risk of severe COVID-19 due to at least one pre-existing medical condition (chronic lung disease, significant cardiac disease, severe obesity, diabetes, liver disease, or HIV infection) regardless of age. Between participants who received Moderna COVID-19 Vaccine and those who received placebo, there were no notable differences in demographics or pre-existing medical conditions.

Efficacy Against COVID-19

COVID-19 was defined based on the following criteria: The participant must have experienced **at least two of the following systemic symptoms: fever (≥38°C), chills, myalgia, headache,** sore throat, new olfactory and taste disorder(s); or the participant must have experienced at least one of the following respiratory signs/symptoms: cough, shortness of breath or difficulty breathing, or clinical or radiographical evidence of pneumonia; and the participant must have at least one

NP swab, nasal swab, or saliva sample (or respiratory sample, if hospitalized) positive for SARS-CoV-2 by RT-PCR. COVID-19 cases were adjudicated by a Clinical Adjudication Committee.

The median length of follow up for efficacy for participants in the study was 9 weeks post Dose 2. There were 11 COVID-19 cases in the Moderna COVID-19 Vaccine group and 185 cases in the placebo group, with a vaccine efficacy of 94.1% (95% confidence interval of 89.3% to 96.8%).

Table 3: Primary Efficacy Analysis: COVID-19* in Participants 18 Years of Age and Older Starting 14 Days After Dose 2 per Adjudication Committee Assessments – Per-Protocol Set

Moderna COVID-19 Vaccine			Placebo			% Vaccine Efficacy (95% CI)†
Participants (N)	COVID-19 Cases (n)	Incidence Rate of COVID-19 per 1,000 Person-Years	Participants (N)	COVID-19 Cases (n)	Incidence Rate of COVID-19 per 1,000 Person-Years	
14,134	11	3.328	14,073	185	56.510	94.1 (89.3, 96.8)

* COVID-19: symptomatic COVID-19 requiring positive RT-PCR result and at least two systemic symptoms or one respiratory symptom. Cases starting 14 days after Dose 2.
† VE and 95% CI from the stratified Cox proportional hazard model.

The subgroup analyses of vaccine efficacy are presented in Table 4.

Table 4: Subgroup Analyses of Vaccine Efficacy: COVID-19* Cases Starting 14 Days After Dose 2 per Adjudication Committee Assessments – Per- Protocol Set

Age Subgroup (Years)	Moderna COVID-19 Vaccine			Placebo			% Vaccine Efficacy (95% CI)*
	Participants (N)	COVID-19 Cases (n)	Incidence Rate of COVID-19 per 1,000 Person-Years	Participants (N)	COVID-19 Cases (n)	Incidence Rate of COVID-19 per 1,000 Person-Years	
18 to <65	10,551	7	2.875	10,521	156	64.625	95.6 (90.6, 97.9)
≥65	3,583	4	4.595	3,552	29	33.728	86.4 (61.4, 95.2)

* COVID-19: symptomatic COVID-19 requiring positive RT-PCR result and at least two systemic symptoms or one respiratory symptom. Cases starting 14 days after Dose 2.
† VE and 95% CI from the stratified Cox proportional hazard model.

Severe COVID-19 was defined based on confirmed COVID-19 as per the primary efficacy endpoint case definition, plus any of the following: Clinical signs indicative of severe systemic illness, respiratory rate ≥30 per minute, heart rate ≥125 beats per minute, SpO2 ≤93% on room

air at sea level or PaO2/FIO2 <300 mm Hg; or respiratory failure or ARDS (defined as needing high-flow oxygen, non-invasive or mechanical ventilation, or ECMO), evidence of shock (systolic blood pressure <90 mmHg, diastolic BP <60 mmHg or requiring vasopressors); or significant acute renal, hepatic, or neurologic dysfunction; or admission to an intensive care unit or death.

Among all participants in the Per-Protocol Set analysis, which included COVID-19 cases confirmed by an adjudication committee, no cases of severe COVID-19 were reported in the Moderna COVID-19 Vaccine group compared with 30 cases reported in the placebo group (incidence rate 9.138 per 1,000 person-years). One PCR-positive case of severe COVID-19 in a vaccine recipient was awaiting adjudication at the time of the analysis.

A separate randomized-controlled study has been conducted in 120 individuals who had undergone various solid organ transplant procedures (heart, kidney, kidney-pancreas, liver, lung, pancreas) a median of 3.57 years previously (range 1.99-6.75 years). A third dose of the Moderna COVID-19 Vaccine was administered to 60 individuals approximately 2 months after they had received a second dose; saline placebo was given to 60 individuals for comparison. Significant increases in levels of SARS-CoV-2 antibodies occurred four weeks after the third dose in 33/60 (55.0%) of the Moderna COVID-19 Vaccine group and 10/57 (17.5%) of the placebo group.

19 HOW SUPPLIED/STORAGE AND HANDLING

Moderna COVID-19 Vaccine Suspension for Intramuscular Injection Multiple-Dose Vials are supplied as follows:

NDC 80777-273-99	Carton of 10 multiple-dose vials, each vial containing a maximum of 11 doses: range 10-11 doses (0.5 mL)
NDC 80777-273-98	Carton of 10 multiple-dose vials, each vial containing a maximum of 15 doses: range 13-15 doses (0.5 mL)

During storage, minimize exposure to room light.

Store frozen between -50° to -15°C (-58° to 5°F). Store in the original carton to protect from light.

Do not store on dry ice or below -50°C (-58°F). Use of dry ice may subject vials to temperatures colder than -50°C (-58°F).

Vials may be stored refrigerated between 2° to 8°C (36° to 46°F) for up to 30 days prior to first use. Do not refreeze.

Vials may be stored between 8° to 25°C (46° to 77°F) for a total of 24 hours.

After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Vials should be discarded 12 hours after the first puncture.

Thawed vials can be handled in room light conditions.

Do not refreeze once thawed.

Transportation of Thawed Vials at 2°C to 8°C (35°F to 46°F)

If transport at -50° to -15°C (-58° to 5°F) is not feasible, available data support transportation of one or more thawed vials for up to 12 hours at 2° to 8°C (35° to 46°F) when shipped using shipping containers which have been qualified to maintain 2° to 8°C (35° to 46°F) and under routine road and air transport conditions with shaking and vibration minimized. Once thawed and transported at 2° to 8°C (35° to 46°F), vials should not be refrozen and should be stored at 2° to 8°C (35° to 46°F) until use.

20 PATIENT COUNSELING INFORMATION

Advise the recipient or caregiver to read the Fact Sheet for Recipients and Caregivers.

The vaccination provider must include vaccination information in the state/local jurisdiction's Immunization Information System (IIS) or other designated system. Advise recipient or caregiver that more information about IISs can be found at: https://www.cdc.gov/vaccines/programs/iis/about.html.

21 CONTACT INFORMATION

For general questions, send an email or call the telephone number provided below.

Email	Telephone number
medinfo@modernatx.com	1-866-MODERNA (1-866-663-3762)

This EUA Prescribing Information may have been updated. For the most recent Full EUA Prescribing Information, please visit www.modernatx.com/covid19vaccine-eua.

Moderna US, Inc.
Cambridge, MA 02139

Patent(s): www.modernatx.com/patents
Revised: Aug/27/2021

FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS)

EMERGENCY USE AUTHORIZATION (EUA) OF THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, Pfizer-BioNTech COVID-19 Vaccine, for active immunization to prevent COVID-19 in individuals 12 years of age and older. Pfizer-BioNTech COVID-19 Vaccine is authorized for use to provide:

- **a two-dose primary series in individuals 12 years of age and older;**
- **a third primary series dose in individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise; and**
- **a single booster dose in individuals:**
  - **65 years of age and older**
  - **18 through 64 years of age at high risk of severe COVID-19**
  - **18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19**

COMIRNATY (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine made by Pfizer for BioNTech that is indicated for active immunization to prevent COVID-19 in individuals 16 years of age and older. It is approved for use as a 2-dose primary series for the prevention of COVID-19 in individuals 16 years of age and older. It is also authorized for emergency use to provide:

- **a two-dose primary series in individuals 12 through 15 years;**
- **a third primary series dose in individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise; and**
- **a single booster dose in individuals:**
  - **65 years of age and older**
  - **18 through 64 years of age at high risk of severe COVID-19**
  - **18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19**

The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the EUA-authorized Pfizer-BioNTech COVID-19 Vaccine have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series.[1]

[1] The licensed vaccine has the same formulation as the EUA-authorized vaccine and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns. The products are legally distinct with certain differences that do not impact safety or effectiveness.

SUMMARY OF INSTRUCTIONS FOR COVID-19 VACCINATION PROVIDERS

Vaccination providers enrolled in the federal COVID-19 Vaccination Program must report all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and cases of COVID-19 that result in hospitalization or death following administration of Pfizer-BioNTech COVID-19 Vaccine. See "MANDATORY REQUIREMENTS FOR PFIZER-BIONTECH COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION" for reporting requirements.

The Pfizer-BioNTech COVID-19 Vaccine is a suspension for intramuscular injection.

Primary Series:

The Pfizer-BioNTech COVID-19 Vaccine is administered as a primary series of two doses (0.3 mL each) 3 weeks apart in individuals 12 years of age or older.

A third dose of the Pfizer-BioNTech COVID-19 Vaccine (0.3 mL) at least 28 days following the second dose is authorized for administration to individuals at least 12 years of age who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

Booster Dose:

A single Pfizer-BioNTech COVID-19 Vaccine booster dose (0.3 mL) may be administered intramuscularly at least 6 months after completing the primary series to individuals:

- 65 years of age and older
- 18 through 64 years of age at high risk of severe COVID-19
- 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19

See this Fact Sheet for instructions for preparation and administration. This Fact Sheet may have been updated. For the most recent Fact Sheet, please see www.cvdvaccine.com.

For information on clinical trials that are testing the use of the Pfizer-BioNTech COVID-19 Vaccine for active immunization against COVID-19, please see www.clinicaltrials.gov.

DESCRIPTION OF COVID-19

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by the novel coronavirus, SARS-CoV-2, that appeared in late 2019. It is predominantly a

respiratory illness that can affect other organs. People with COVID-19 have reported a wide range of symptoms, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

DOSAGE AND ADMINISTRATION

Storage and Handling

During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

Do not refreeze thawed vials.

Frozen Vials Prior to Use

Cartons of Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vials arrive in thermal containers with dry ice. Once received, remove the vial cartons immediately from the thermal container and preferably store in an ultra-low temperature freezer between -90ºC to -60ºC (-130ºF to -76ºF) until the expiry date printed on the label. This information in the package insert supersedes the storage conditions printed on the vial cartons.

Cartons and vials of Pfizer-BioNTech COVID-19 Vaccine with an expiry date of May 2021 through February 2022 printed on the label may remain in use for 3 months beyond the printed date as long as approved storage conditions between -90ºC to -60ºC (-130ºF to -76ºF) have been maintained. Updated expiry dates are shown below.

Printed Expiry Date		Updated Expiry Date
May 2021	→	August 2021
June 2021	→	September 2021
July 2021	→	October 2021
August 2021	→	November 2021
September 2021	→	December 2021
October 2021	→	January 2022
November 2021	→	February 2022
December 2021	→	March 2022
January 2022	→	April 2022
February 2022	→	May 2022

If not stored between -90ºC to -60ºC (-130ºF to -76ºF), vials may be stored at -25°C to -15°C (-13°F to 5°F) for up to 2 weeks. Vials must be kept frozen and protected from light until ready to use. Vials stored at -25°C to -15°C (-13°F to 5°F) for up to 2 weeks may be returned one time to the recommended storage condition of -90ºC

to -60ºC (-130ºF to -76ºF). Total cumulative time the vials are stored at -25°C to -15°C (-13°F to 5°F) should be tracked and should not exceed 2 weeks.

If an ultra-low temperature freezer is not available, the thermal container in which the Pfizer-BioNTech COVID-19 Vaccine arrives may be used as temporary storage when consistently re-filled to the top of the container with dry ice. Refer to the re-icing guidelines packed in the original thermal container for instructions regarding the use of the thermal container for temporary storage. The thermal container maintains a temperature range of -90ºC to -60ºC (-130ºF to -76ºF). Storage of the vials between -96°C to -60°C (-141°F to -76°F) is not considered an excursion from the recommended storage condition.

Transportation of Frozen Vials

If local redistribution is needed and full cartons containing vials cannot be transported at -90°C to -60°C (-130°F to -76°F), vials may be transported at -25°C to -15°C (-13°F to 5°F). Any hours used for transport at -25°C to -15°C (-13°F to 5°F) count against the 2-week limit for storage at -25°C to -15°C (-13°F to 5°F). Frozen vials transported at -25°C to -15°C (-13°F to 5°F) may be returned one time to the recommended storage condition of -90ºC to -60ºC (-130ºF to -76ºF).

Thawed Vials Before Dilution

Thawed Under Refrigeration
Thaw and then store undiluted vials in the refrigerator [2ºC to 8ºC (35ºF to 46ºF)] for up to 1 month. A carton of 25 vials or 195 vials may take up to 2 or 3 hours, respectively, to thaw in the refrigerator, whereas a fewer number of vials will thaw in less time.

Thawed at Room Temperature
For immediate use, thaw undiluted vials at room temperature [up to 25ºC (77ºF)] for 30 minutes. Thawed vials can be handled in room light conditions. Vials must reach room temperature before dilution.

Undiluted vials may be stored at room temperature for no more than 2 hours.

Transportation of Thawed Vials

Available data support transportation of one or more thawed vials at 2°C to 8°C (35°F to 46°F) for up to 12 hours.

Vials After Dilution

- After dilution, store vials between 2°C to 25°C (35°F to 77°F) and use within 6 hours from the time of dilution.
- During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.
- Any vaccine remaining in vials must be discarded after 6 hours.
- Do not refreeze.

Dosing and Schedule

Primary Series:

The Pfizer-BioNTech COVID-19 Vaccine is administered intramuscularly as a primary series of two doses (0.3 mL each) 3 weeks apart to individuals 12 years of age and older.

A third dose of the Pfizer-BioNTech COVID-19 vaccine (0.3 mL) at least 28 days following the second dose is authorized for administration to individuals at least 12 years of age who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

Booster Dose:

A single Pfizer-BioNTech COVID-19 Vaccine booster dose (0.3 mL) may be administered intramuscularly at least 6 months after completing the primary series to individuals:

- 65 years of age and older
- 18 through 64 years of age at high risk of severe COVID-19
- 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19

The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the EUA-authorized Pfizer-BioNTech COVID-19 Vaccine have the same formulation and can be used interchangeably to provide the COVID-19 primary vaccination series or booster dose.[2]

There are no data available on the interchangeability of the Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY (COVID-19 Vaccine, mRNA) with other authorized COVID-19 vaccines to complete the primary vaccination series or booster dose.

[2] The licensed vaccine has the same formulation as the EUA-authorized vaccine and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns. The products are legally distinct with certain differences that do not impact safety or effectiveness.

Dose Preparation

Prior to Dilution

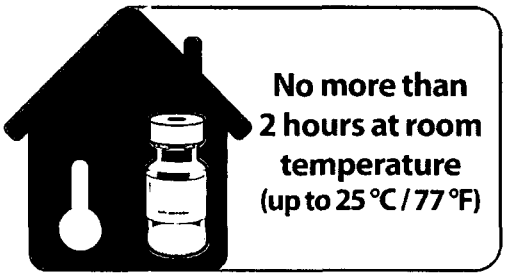
- The Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vial contains a volume of 0.45 mL, supplied as a frozen suspension that does not contain preservative. Each vial must be thawed and diluted prior to administration.
- Vials may be thawed in the refrigerator [2°C to 8°C (35°F to 46°F)] or at room temperature [up to 25°C (77°F)] *(see Storage and Handling)*.
- Refer to thawing instructions in the panels below.

Dilution

Dilute the vial contents using 1.8 mL of 0.9% Sodium Chloride Injection, USP (not provided) to form the Pfizer-BioNTech COVID-19 Vaccine. ONLY use 0.9% Sodium Chloride Injection, USP as the diluent. This diluent is not packaged with the vaccine and must be sourced separately. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent. Do not add more than 1.8 mL of diluent.

After dilution, one vial contains 6 doses of 0.3 mL. Vial labels and cartons may state that after dilution, a vial contains 5 doses of 0.3 mL. The information in this Fact Sheet regarding the number of doses per vial after dilution supersedes the number of doses stated on vial labels and cartons.

- Refer to dilution and dose preparation instructions in the panels below.

THAWING PRIOR TO DILUTION	
	• Thaw vial(s) of Pfizer-BioNTech COVID-19 Vaccine before use either by: o Allowing vial(s) to thaw in the refrigerator [2°C to 8°C (35°F to 46°F)]. A carton of vials may take up to 3 hours to thaw, and thawed vials can be stored in the refrigerator for up to 1 month. o Allowing vial(s) to sit at room temperature [up to 25°C (77°F)] for 30 minutes. • Using either thawing method, vials must reach room temperature before dilution and must be diluted within 2 hours.

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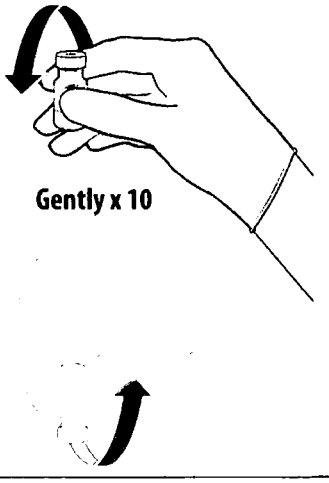
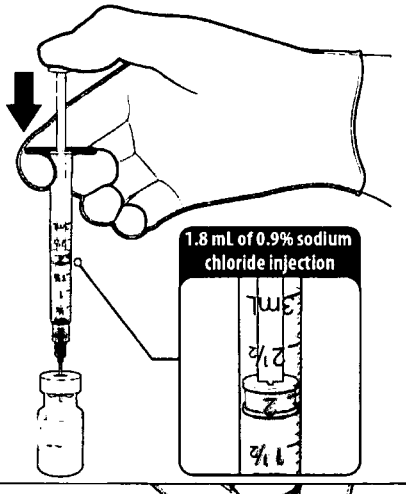
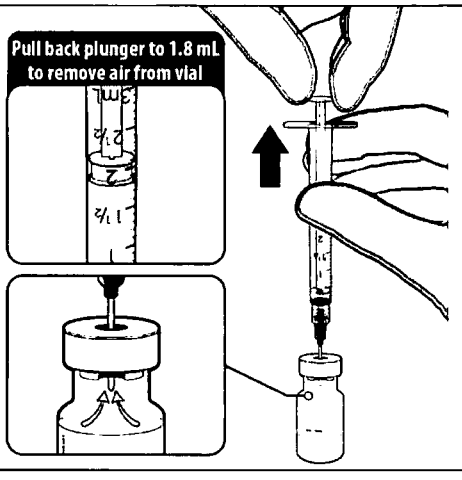
<tr><td> 
</td><td>

- Before dilution invert vaccine vial gently 10 times.
- Do not shake.
- Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain white to off-white opaque amorphous particles.
- Do not use if liquid is discolored or if other particles are observed.

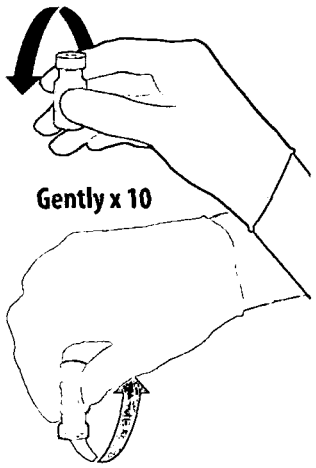
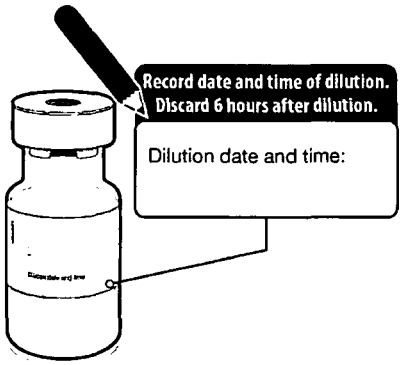
</td></tr>
<tr><td colspan="2">DILUTION</td></tr>
<tr><td> 
</td><td>

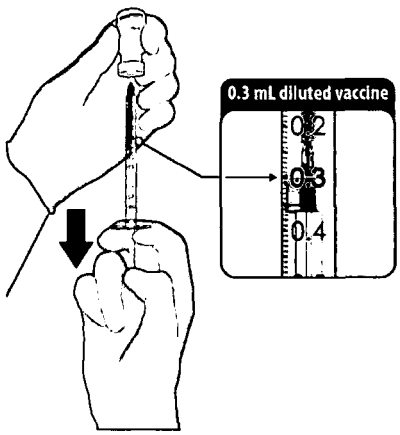
- Obtain sterile 0.9% Sodium Chloride Injection, USP. Use only this as the diluent.
- Using aseptic technique, withdraw 1.8 mL of diluent into a transfer syringe (21-gauge or narrower needle).
- Cleanse the vaccine vial stopper with a single-use antiseptic swab.
- Add 1.8 mL of 0.9% Sodium Chloride Injection, USP into the vaccine vial.

</td></tr>
<tr><td> 
</td><td>

- Equalize vial pressure before removing the needle from the vial by withdrawing 1.8 mL air into the empty diluent syringe.

</td></tr>
</table>

	• Gently invert the vial containing the Pfizer-BioNTech COVID-19 Vaccine 10 times to mix. • Do not shake. • Inspect the vaccine in the vial. • The vaccine will be an off-white suspension. Do not use if vaccine is discolored or contains particulate matter.
	• Record the date and time of dilution on the Pfizer-BioNTech COVID-19 Vaccine vial label. • Store between 2°C to 25°C (35°F to 77°F). • Discard any unused vaccine 6 hours after dilution.

PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF PFIZER-BIONTECH COVID-19 VACCINE	
	• Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.3 mL of the Pfizer-BioNTech COVID-19 Vaccine preferentially using a low dead-volume syringe and/or needle. • Each dose must contain 0.3 mL of vaccine. • If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume. • Administer immediately.

Administration

Visually inspect each dose in the dosing syringe prior to administration. The vaccine will be an off-white suspension. During the visual inspection,

- verify the final dosing volume of 0.3 mL.
- confirm there are no particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains particulate matter.

Administer the Pfizer-BioNTech COVID-19 Vaccine intramuscularly.

After dilution, vials of Pfizer-BioNTech COVID-19 Vaccine contain six doses of 0.3 mL of vaccine. Low dead-volume syringes and/or needles can be used to extract six doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial. Irrespective of the type of syringe and needle:

- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and content.
- Do not pool excess vaccine from multiple vials.

Contraindications

Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine *(see Full EUA Prescribing Information)*.

Warnings

Management of Acute Allergic Reactions

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine.

Monitor Pfizer-BioNTech COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention (CDC) guidelines (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html).

Myocarditis and Pericarditis

Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The observed risk is higher among males under 40 years of age than among females and older males. The observed risk is highest in males 12 through 17 years of age. Although some cases required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with conservative

management. Information is not yet available about potential long-term sequelae. The CDC has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html).

Syncope

Syncope (fainting) may occur in association with administration of injectable vaccines, in particular in adolescents. Procedures should be in place to avoid injury from fainting.

Altered Immunocompetence

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Pfizer-BioNTech COVID-19 Vaccine.

Limitation of Effectiveness

Pfizer-BioNTech COVID-19 Vaccine may not protect all vaccine recipients.

Adverse Reactions

Adverse Reactions in Clinical Trials
Adverse reactions following the Pfizer-BioNTech COVID-19 Vaccine that have been reported in clinical trials include injection site pain, fatigue, headache, muscle pain, chills, joint pain, fever, injection site swelling, injection site redness, nausea, malaise, lymphadenopathy, and decreased appetite *(see Full EUA Prescribing Information)*.

Adverse Reactions in Post Authorization Experience
Severe allergic reactions, including anaphylaxis, and other hypersensitivity reactions (e.g., rash, pruritus, urticaria, angioedema), diarrhea, vomiting, pain in extremity (arm), and syncope have been reported following administration of the Pfizer-BioNTech COVID-19 Vaccine outside of clinical trials.

Myocarditis and pericarditis have been reported following administration of the Pfizer-BioNTech COVID-19 Vaccine outside of clinical trials.

Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Pfizer-BioNTech COVID-19 Vaccine.

Use with Other Vaccines

There is no information on the co-administration of the Pfizer-BioNTech COVID-19 Vaccine with other vaccines.

INFORMATION TO PROVIDE TO VACCINE RECIPIENTS/CAREGIVERS

As the vaccination provider, you must communicate to the recipient or their caregiver, information consistent with the "Vaccine Information Fact Sheet for Recipients and Caregivers" (and provide a copy or direct the individual to the website www.cvdvaccine.com to obtain the Vaccine Information Fact Sheet) prior to the individual receiving each dose of Pfizer-BioNTech COVID-19 Vaccine, including:

- FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine, which is not an FDA-approved vaccine.
- The recipient or their caregiver has the option to accept or refuse Pfizer-BioNTech COVID-19 Vaccine.
- The significant known and potential risks and benefits of Pfizer-BioNTech COVID-19 Vaccine, and the extent to which such risks and benefits are unknown.
- Information about available alternative vaccines and the risks and benefits of those alternatives.

For information on clinical trials that are testing the use of the Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19, please see www.clinicaltrials.gov.

Provide a vaccination card to the recipient or their caregiver with the date when the recipient needs to return for the second dose of Pfizer-BioNTech COVID-19 Vaccine.

Provide the v-safe information sheet to vaccine recipients/caregivers and encourage vaccine recipients to participate in v-safe. V-safe is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. V-safe asks questions that help CDC monitor the safety of COVID-19 vaccines. V-safe also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information, visit: www.cdc.gov/vsafe.

MANDATORY REQUIREMENTS FOR PFIZER-BIONTECH COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION[3]

In order to mitigate the risks of using this unapproved product under EUA and to optimize the potential benefit of Pfizer-BioNTech COVID-19 Vaccine, the following items are required. Use of unapproved Pfizer-BioNTech COVID-19 Vaccine for active immunization to prevent COVID-19 under this EUA is limited to the following (all requirements **must** be met):

1. Pfizer-BioNTech COVID-19 Vaccine is authorized for use in individuals 12 years of age and older.

[3] Vaccination providers administering COMIRNATY (COVID-19 Vaccine, mRNA) must adhere to the same reporting requirements.

2. The vaccination provider must communicate to the individual receiving the Pfizer-BioNTech COVID-19 Vaccine or their caregiver, information consistent with the "Vaccine Information Fact Sheet for Recipients and Caregivers" prior to the individual receiving Pfizer-BioNTech COVID-19 Vaccine.

3. The vaccination provider must include vaccination information in the state/local jurisdiction's Immunization Information System (IIS) or other designated system.

4. The vaccination provider is responsible for mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS):
   - vaccine administration errors whether or not associated with an adverse event,
   - serious adverse events* (irrespective of attribution to vaccination),
   - cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and
   - cases of COVID-19 that result in hospitalization or death.

   Complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html. For further assistance with reporting to VAERS call 1-800-822-7967. The reports should include the words "Pfizer-BioNTech COVID-19 Vaccine EUA" in the description section of the report.

5. The vaccination provider is responsible for responding to FDA requests for information about vaccine administration errors, adverse events, cases of MIS in adults and children, and cases of COVID-19 that result in hospitalization or death following administration of Pfizer-BioNTech COVID-19 Vaccine to recipients.

* Serious adverse events are defined as:
- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect;
- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.

OTHER ADVERSE EVENT REPORTING TO VAERS AND PFIZER INC.

Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.

To the extent feasible, report adverse events to Pfizer Inc. using the contact information below or by providing a copy of the VAERS form to Pfizer Inc.

Website	Fax number	Telephone number
www.pfizersafetyreporting.com	1-866-635-8337	1-800-438-1985

ADDITIONAL INFORMATION

For general questions, visit the website or call the telephone number provided below.

To access the most recent Pfizer-BioNTech COVID-19 Vaccine Fact Sheets, please scan the QR code provided below.

Global website	Telephone number
www.cvdvaccine.com	1-877-829-2619 (1-877-VAX-CO19)

AVAILABLE ALTERNATIVES

COMIRNATY (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine made by Pfizer for BioNTech. It is approved as a 2-dose primary series for use in individuals 16 years of age and older. COMIRNATY (COVID-19 Vaccine, mRNA) is also authorized for emergency use to provide:

- a two-dose primary series in individuals 12 through 15 years;
- a third primary series dose in individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise; and
- a single booster dose in individuals:
  - 65 years of age and older
  - 18 through 64 years of age at high risk of severe COVID-19
  - 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19

COMIRNATY (COVID-19 Vaccine, mRNA) has the same formulation as the Pfizer-BioNTech COVID-19 Vaccine. These vaccines can be used interchangeably to provide the COVID-19 vaccination series.[4]

There may be clinical trials or availability under EUA of other COVID-19 vaccines.

FEDERAL COVID-19 VACCINATION PROGRAM

This vaccine is being made available for emergency use exclusively through the CDC COVID-19 Vaccination Program (the Vaccination Program). Healthcare providers must enroll as providers in the Vaccination Program and comply with the provider requirements. Vaccination providers may not charge any fee for the vaccine and may not charge the vaccine recipient any out-of-pocket charge for administration. However, vaccination providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient (private insurance, Medicare, Medicaid, Health Resources & Services Administration [HRSA] COVID-19 Uninsured Program for non-insured recipients). For information regarding provider requirements and enrollment in the CDC COVID-19 Vaccination Program, see https://www.cdc.gov/vaccines/covid-19/provider-enrollment.html.

Individuals becoming aware of any potential violations of the CDC COVID-19 Vaccination Program requirements are encouraged to report them to the Office of the Inspector General, U.S. Department of Health and Human Services, at 1-800-HHS-TIPS or https://TIPS.HHS.GOV.

AUTHORITY FOR ISSUANCE OF THE EUA

The Secretary of Health and Human Services (HHS) has declared a public health emergency that justifies the emergency use of drugs and biological products during the COVID-19 pandemic. In response, FDA has issued an EUA for the unapproved product, Pfizer-BioNTech COVID-19 Vaccine, for active immunization against COVID-19. Pfizer-BioNTech COVID-19 Vaccine is authorized for use to provide:

- a two-dose primary series in individuals 12 years of age and older;
- a third primary series dose in individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise; and
- a single booster dose in individuals:
  - 65 years of age and older
  - 18 through 64 years of age at high risk of severe COVID-19
  - 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19

[4] The licensed vaccine has the same formulation as the EUA-authorized vaccine and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns. The products are legally distinct with certain differences that do not impact safety or effectiveness.

FDA-approved COMIRNATY is also authorized for use to provide:

- a two-dose primary series in individuals 12 through 15 years;
- a third primary series dose in individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise; and
- a single booster dose in individuals:
  - 65 years of age and older
  - 18 through 64 years of age at high risk of severe COVID-19
  - 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19

FDA issued this EUA, based on Pfizer-BioNTech's request and submitted data.

For the authorized uses, although limited scientific information is available, based on the totality of the scientific evidence available to date, it is reasonable to believe that the Pfizer-BioNTech COVID-19 Vaccine and COMIRNATY may be effective for the prevention of COVID-19 in individuals as specified in the *Full EUA Prescribing Information*.

This EUA for the Pfizer-BioNTech COVID-19 Vaccine and COMIRNATY will end when the Secretary of HHS determines that the circumstances justifying the EUA no longer exist or when there is a change in the approval status of the product such that an EUA is no longer needed.

For additional information about Emergency Use Authorization visit FDA at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

The Countermeasures Injury Compensation Program

The Countermeasures Injury Compensation Program (CICP) is a federal program that has been created to help pay for related costs of medical care and other specific expenses to compensate people injured after use of certain medical countermeasures. Medical countermeasures are specific vaccines, medications, devices, or other items used to prevent, diagnose, or treat the public during a public health emergency or a security threat. For more information about CICP regarding the Pfizer-BioNTech COVID-19 Vaccine used to prevent COVID-19, visit www.hrsa.gov/cicp, email cicp@hrsa.gov, or call: 1-855-266-2427.

Pfizer

Manufactured by
Pfizer Inc., New York, NY 10017

BIONTECH

Manufactured for
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany

LAB-1450-13.4

Revised: 22 September 2021

END SHORT VERSION FACT SHEET
Long Version (Full EUA Prescribing Information) Begins On Next Page

FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION

PFIZER-BIONTECH COVID-19 VACCINE

FULL EMERGENCY USE AUTHORIZATION PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full emergency use authorization prescribing information are not listed.

FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION

1 AUTHORIZED USE

Pfizer-BioNTech COVID-19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 years of age and older.

2 DOSAGE AND ADMINISTRATION

For intramuscular injection only.

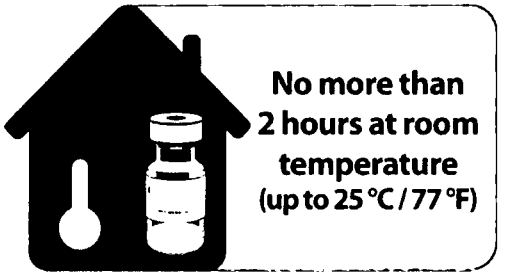
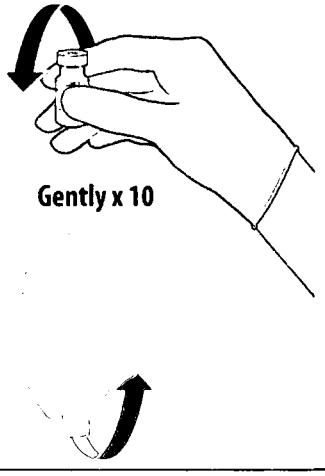
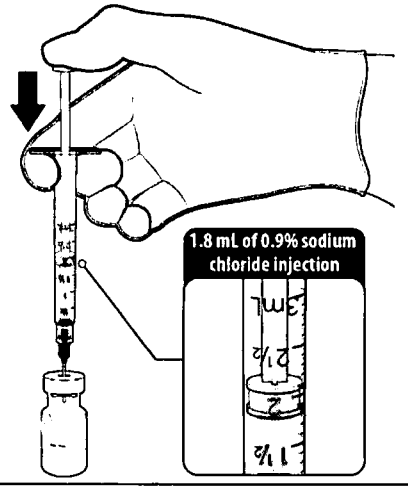
2.1 Preparation for Administration

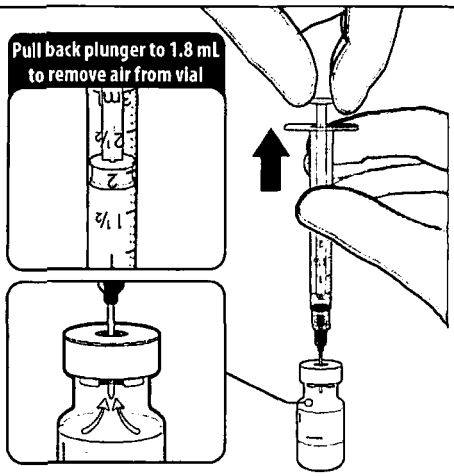
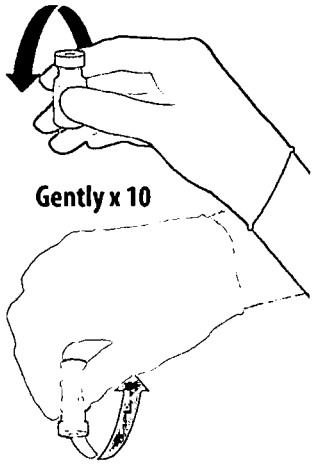
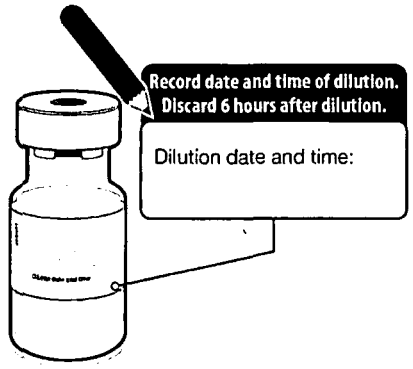
Prior to Dilution

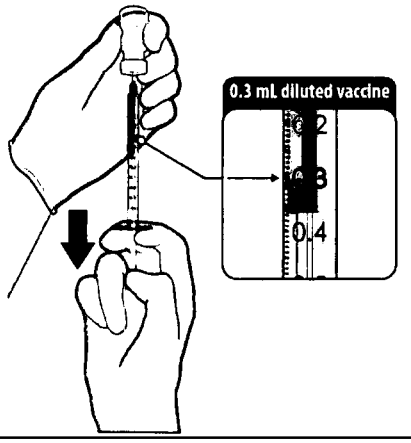
- The Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vial contains a volume of 0.45 mL, supplied as a frozen suspension that does not contain preservative. Each vial must be thawed and diluted prior to administration.
- Vials may be thawed in the refrigerator [2°C to 8°C (35°F to 46°F)] or at room temperature [up to 25°C (77°F)] *[see How Supplied/Storage and Handling (19)]*.
- Refer to thawing instructions in the panels below.

Dilution

- Dilute the vial contents using 1.8 mL of 0.9% Sodium Chloride Injection, USP (not provided) to form the Pfizer-BioNTech COVID-19 Vaccine. Do not add more than 1.8 mL of diluent.
- ONLY use 0.9% Sodium Chloride Injection, USP as the diluent. This diluent is not packaged with the vaccine and must be sourced separately. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.
- After dilution, one vial contains 6 doses of 0.3 mL. Vial labels and cartons may state that after dilution, a vial contains 5 doses of 0.3 mL. The information in this Full EUA Prescribing Information regarding the number of doses per vial after dilution supersedes the number of doses stated on vial labels and cartons.
- Refer to dilution and dose preparation instructions in the panels below.

THAWING PRIOR TO DILUTION	
	• Thaw vial(s) of Pfizer-BioNTech COVID-19 Vaccine before use either by: o Allowing vial(s) to thaw in the refrigerator [2°C to 8°C (35°F to 46°F)]. A carton of vials may take up to 3 hours to thaw, and thawed vials can be stored in the refrigerator for up to 1 month. o Allowing vial(s) to sit at room temperature [up to 25°C (77°F)] for 30 minutes. • Using either thawing method, vials must reach room temperature before dilution and must be diluted within 2 hours.
	• Before dilution invert vaccine vial gently 10 times. • Do not shake. • Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain white to off-white opaque amorphous particles. • Do not use if liquid is discolored or if other particles are observed.
DILUTION	
	• Obtain sterile 0.9% Sodium Chloride Injection, USP. Use only this as the diluent. • Using aseptic technique, withdraw 1.8 mL of diluent into a transfer syringe (21-gauge or narrower needle). • Cleanse the vaccine vial stopper with a single-use antiseptic swab. • Add 1.8 mL of 0.9% Sodium Chloride Injection, USP into the vaccine vial.

	• Equalize vial pressure before removing the needle from the vial by withdrawing 1.8 mL air into the empty diluent syringe.
	• Gently invert the vial containing the Pfizer-BioNTech COVID-19 Vaccine 10 times to mix. • Do not shake. • Inspect the vaccine in the vial. • The vaccine will be an off-white suspension. Do not use if vaccine is discolored or contains particulate matter.
	• Record the date and time of dilution on the Pfizer-BioNTech COVID-19 Vaccine vial label. • Store between 2°C to 25°C (35°F to 77°F). • Discard any unused vaccine 6 hours after dilution.

PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF PFIZER-BIONTECH COVID-19 VACCINE	
	• Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.3 mL of the Pfizer-BioNTech COVID-19 Vaccine preferentially using low dead-volume syringes and/or needles. • Each dose must contain 0.3 mL of vaccine. • If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume. • Administer immediately.

2.2 Administration Information

Visually inspect each dose in the dosing syringe prior to administration. The vaccine will be an off-white suspension. During the visual inspection,

- verify the final dosing volume of 0.3 mL.
- confirm there are no particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains particulate matter.

Administer the Pfizer-BioNTech COVID-19 Vaccine intramuscularly.

After dilution, vials of Pfizer-BioNTech COVID-19 Vaccine contain six doses of 0.3 mL of vaccine. Low dead-volume syringes and/or needles can be used to extract six doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial. Irrespective of the type of syringe and needle:

- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
- Do not pool excess vaccine from multiple vials.

2.3 Vaccination Schedule

Primary Series:

The Pfizer-BioNTech COVID-19 Vaccine is administered intramuscularly as a primary series of two doses (0.3 mL each) three weeks apart in individuals 12 years of age and older.

A third dose of the Pfizer-BioNTech COVID-19 vaccine (0.3 mL) at least 28 days following the second dose is authorized for administration to individuals at least 12 years of age who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

Booster Dose:

A single Pfizer-BioNTech COVID-19 Vaccine booster dose (0.3 mL) may be administered intramuscularly at least 6 months after completing the primary series to individuals:

- 65 years of age and older
- 18 through 64 years of age at high risk of severe COVID-19
- 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19

The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the EUA-authorized Pfizer-BioNTech COVID-19 Vaccine have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series.[5] There are no data available on the interchangeability of the Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY (COVID-19 Vaccine, mRNA) with other authorized COVID-19 vaccines.

3 DOSAGE FORMS AND STRENGTHS

Pfizer-BioNTech COVID-19 Vaccine is a suspension for injection. After preparation, a single dose is 0.3 mL *[see Dosage and Administration (2.1)]*.

4 CONTRAINDICATIONS

Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine *[see Description (13)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Management of Acute Allergic Reactions

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine.

Monitor Pfizer-BioNTech COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention (CDC) guidelines (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html).

5.2 Myocarditis and Pericarditis

Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The observed risk is higher among males under 40 years of age than among females and older males. The observed risk is highest in males 12 through 17 years of age. Although some cases required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with conservative management. Information is not yet available about potential long-term sequelae. The CDC has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html).

[5] The licensed vaccine has the same formulation as the EUA-authorized vaccine and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns. The products are legally distinct with certain differences that do not impact safety or effectiveness.

5.3 Syncope

Syncope (fainting) may occur in association with administration of injectable vaccines, in particular in adolescents. Procedures should be in place to avoid injury from fainting.

5.4 Altered Immunocompetence

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Pfizer-BioNTech COVID-19 Vaccine.

5.5 Limitation of Effectiveness

The Pfizer-BioNTech COVID-19 Vaccine may not protect all vaccine recipients.

6 OVERALL SAFETY SUMMARY

It is MANDATORY for vaccination providers to report to the Vaccine Adverse Event Reporting System (VAERS) all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and hospitalized or fatal cases of COVID-19 following vaccination with the Pfizer-BioNTech COVID-19 Vaccine.[6] To the extent feasible, provide a copy of the VAERS form to Pfizer Inc. Please see the REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS section for details on reporting to VAERS and Pfizer Inc.

In clinical studies of participants 16 years of age and older, adverse reactions following administration of the primary series included pain at the injection site (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), fever (14.2%), injection site swelling (10.5%), injection site redness (9.5%), nausea (1.1%), malaise (0.5%), and lymphadenopathy (0.3%).

In a clinical study in adolescents 12 through 15 years of age, adverse reactions following administration of the primary series included pain at the injection site (90.5%), fatigue (77.5%), headache (75.5%), chills (49.2%), muscle pain (42.2%), fever (24.3%), joint pain (20.2%), injection site swelling (9.2%), injection site redness (8.6%), lymphadenopathy (0.8%), and nausea (0.4%).

In a clinical study of participants 18 through 55 years of age, the most commonly reported adverse reactions (≥10%) following administration of a booster dose were pain at the injection site (83.0%), fatigue (63.7%), headache (48.4%), muscle pain (39.1%), chills (29.1%), and joint pain (25.3%).

Severe allergic reactions, including anaphylaxis, have been reported following administration of the Pfizer-BioNTech COVID-19 Vaccine outside of clinical trials.

Myocarditis and pericarditis have been reported following administration of the Pfizer-BioNTech COVID-19 Vaccine outside of clinical trials.

[6] Vaccination providers administering COMIRNATY (COVID-19 Vaccine, mRNA) must adhere to the same reporting requirements.

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Primary Series

The safety of the primary series Pfizer-BioNTech COVID-19 Vaccine was evaluated in participants 12 years of age and older in two clinical studies conducted in the United States, Europe, Turkey, South Africa, and South America. Study BNT162-01 (Study 1) was a Phase 1/2, two-part, dose-escalation trial that enrolled 60 participants, 18 through 55 years of age. Study C4591001 (Study 2) is a Phase 1/2/3, multicenter, multinational, randomized, saline placebo-controlled, observer-blind, dose-finding, vaccine candidate-selection (Phase 1) and efficacy (Phase 2/3) study that has enrolled approximately 46,000 participants, 12 years of age or older. Of these, approximately 43,448 participants (21,720 Pfizer-BioNTech COVID-19 Vaccine; 21,728 placebo) in Phase 2/3 are 16 years of age or older (including 138 and 145 adolescents 16 and 17 years of age in the vaccine and placebo groups, respectively) and 2,260 adolescents are 12 through 15 years of age (1,131 and 1,129 in the vaccine and placebo groups, respectively).

In Study 2, all participants 12 to <16 years of age, and participants 16 years of age and older in the reactogenicity subset, were monitored for solicited local and systemic reactions and use of antipyretic medication after each vaccination in an electronic diary. Participants are being monitored for unsolicited adverse events, including serious adverse events, throughout the study [from Dose 1 through 1 month (all unsolicited adverse events) or 6 months (serious adverse events) after the last vaccination]. Tables 1 through 6 present the frequency and severity of solicited local and systemic reactions, respectively, within 7 days following each dose of Pfizer-BioNTech COVID 19 Vaccine and placebo.

Participants 16 Years of Age and Older

At the time of the analysis of Study 2 for the EUA, 37,586 (18,801 Pfizer-BioNTech COVID-19 Vaccine and 18,785 placebo) participants 16 years of age or older had been followed for a median of 2 months after the second dose of Pfizer-BioNTech COVID-19 Vaccine.

The safety evaluation in Study 2 is ongoing. The safety population includes participants 16 years and older enrolled by October 9, 2020, and includes safety data accrued through November 14, 2020.

Demographic characteristics in Study 2 were generally similar with regard to age, gender, race, and ethnicity among participants who received Pfizer-BioNTech COVID-19 Vaccine and those who received placebo. Overall, among the total participants who received either the Pfizer-BioNTech COVID-19 Vaccine or placebo, 50.6% were male and 49.4% were female, 83.1% were White, 9.1% were Black or African American, 28.0% were Hispanic/Latino, 4.3% were Asian, and 0.5% were American Indian/Alaska Native.

Solicited Local and Systemic Adverse Reactions

Across both age groups, 18 through 55 years of age and 56 years and older, the mean duration of pain at the injection site after Dose 2 was 2.5 days (range 1 to 36 days), for redness 2.6 days (range 1 to 34 days), and for swelling 2.3 days (range 1 to 34 days) for participants in the Pfizer-BioNTech COVID-19 Vaccine group.

Solicited reactogenicity data in 16 and 17 year-old participants are limited.

Table 1: Study 2 – Frequency and Percentages of Participants with Solicited Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 18 Through 55 Years of Age‡ – Reactogenicity Subset of the Safety Population*

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=2291 n[b] (%)	Placebo Dose 1 N[a]=2298 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=2098 n[b] (%)	Placebo Dose 2 N[a]=2103 n[b] (%)
Redness[c]				
Any (>2 cm)	104 (4.5)	26 (1.1)	123 (5.9)	14 (0.7)
Mild	70 (3.1)	16 (0.7)	73 (3.5)	8 (0.4)
Moderate	28 (1.2)	6 (0.3)	40 (1.9)	6 (0.3)
Severe	6 (0.3)	4 (0.2)	10 (0.5)	0 (0.0)
Swelling[c]				
Any (>2 cm)	132 (5.8)	11 (0.5)	132 (6.3)	5 (0.2)
Mild	88 (3.8)	3 (0.1)	80 (3.8)	3 (0.1)
Moderate	39 (1.7)	5 (0.2)	45 (2.1)	2 (0.1)
Severe	5 (0.2)	3 (0.1)	7 (0.3)	0 (0.0)
Pain at the injection site[d]				
Any	1904 (83.1)	322 (14.0)	1632 (77.8)	245 (11.7)
Mild	1170 (51.1)	308 (13.4)	1039 (49.5)	225 (10.7)
Moderate	710 (31.0)	12 (0.5)	568 (27.1)	20 (1.0)
Severe	24 (1.0)	2 (0.1)	25 (1.2)	0 (0.0)

Note: Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after vaccination.
a. N = Number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose.
b. n = Number of participants with the specified reaction.
c. Mild: >2.0 to ≤5.0 cm; Moderate: >5.0 to ≤10.0 cm; Severe: >10.0 cm.
d. Mild: does not interfere with activity; Moderate: interferes with activity; Severe: prevents daily activity.
‡ Eight participants were between 16 and 17 years of age.
* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

Table 2: Study 2 – Frequency and Percentages of Participants with Solicited Systemic Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 18 Through 55 Years of Age‡ – Reactogenicity Subset of the Safety Population*

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=2291 n[b] (%)	Placebo Dose 1 N[a]=2298 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=2098 n[b] (%)	Placebo Dose 2 N[a]=2103 n[b] (%)
Fever				
≥38.0°C	85 (3.7)	20 (0.9)	331 (15.8)	10 (0.5)
≥38.0°C to 38.4°C	64 (2.8)	10 (0.4)	194 (9.2)	5 (0.2)
>38.4°C to 38.9°C	15 (0.7)	5 (0.2)	110 (5.2)	3 (0.1)
>38.9°C to 40.0°C	6 (0.3)	3 (0.1)	26 (1.2)	2 (0.1)
>40.0°C	0 (0.0)	2 (0.1)	1 (0.0)	0 (0.0)
Fatigue[c]				
Any	1085 (47.4)	767 (33.4)	1247 (59.4)	479 (22.8)
Mild	597 (26.1)	467 (20.3)	442 (21.1)	248 (11.8)
Moderate	455 (19.9)	289 (12.6)	708 (33.7)	217 (10.3)
Severe	33 (1.4)	11 (0.5)	97 (4.6)	14 (0.7)

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=2291 n[b] (%)	Placebo Dose 1 N[a]=2298 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=2098 n[b] (%)	Placebo Dose 2 N[a]=2103 n[b] (%)
Headache[c]				
Any	959 (41.9)	775 (33.7)	1085 (51.7)	506 (24.1)
Mild	628 (27.4)	505 (22.0)	538 (25.6)	321 (15.3)
Moderate	308 (13.4)	251 (10.9)	480 (22.9)	170 (8.1)
Severe	23 (1.0)	19 (0.8)	67 (3.2)	15 (0.7)
Chills[c]				
Any	321 (14.0)	146 (6.4)	737 (35.1)	79 (3.8)
Mild	230 (10.0)	111 (4.8)	359 (17.1)	65 (3.1)
Moderate	82 (3.6)	33 (1.4)	333 (15.9)	14 (0.7)
Severe	9 (0.4)	2 (0.1)	45 (2.1)	0 (0.0)
Vomiting[d]				
Any	28 (1.2)	28 (1.2)	40 (1.9)	25 (1.2)
Mild	24 (1.0)	22 (1.0)	28 (1.3)	16 (0.8)
Moderate	4 (0.2)	5 (0.2)	8 (0.4)	9 (0.4)
Severe	0 (0.0)	1 (0.0)	4 (0.2)	0 (0.0)
Diarrhea[e]				
Any	255 (11.1)	270 (11.7)	219 (10.4)	177 (8.4)
Mild	206 (9.0)	217 (9.4)	179 (8.5)	144 (6.8)
Moderate	46 (2.0)	52 (2.3)	36 (1.7)	32 (1.5)
Severe	3 (0.1)	1 (0.0)	4 (0.2)	1 (0.0)
New or worsened muscle pain[c]				
Any	487 (21.3)	249 (10.8)	783 (37.3)	173 (8.2)
Mild	256 (11.2)	175 (7.6)	326 (15.5)	111 (5.3)
Moderate	218 (9.5)	72 (3.1)	410 (19.5)	59 (2.8)
Severe	13 (0.6)	2 (0.1)	47 (2.2)	3 (0.1)
New or worsened joint pain[c]				
Any	251 (11.0)	138 (6.0)	459 (21.9)	109 (5.2)
Mild	147 (6.4)	95 (4.1)	205 (9.8)	54 (2.6)
Moderate	99 (4.3)	43 (1.9)	234 (11.2)	51 (2.4)
Severe	5 (0.2)	0 (0.0)	20 (1.0)	4 (0.2)
Use of antipyretic or pain medication[f]	638 (27.8)	332 (14.4)	945 (45.0)	266 (12.6)

Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) from Day 1 to Day 7 after each dose.

a. N = Number of participants reporting at least 1 yes or no response for the specified event after the specified dose.
b. n = Number of participants with the specified reaction.
c. Mild: does not interfere with activity; Moderate: some interference with activity; Severe: prevents daily activity.
d. Mild: 1 to 2 times in 24 hours; Moderate: >2 times in 24 hours; Severe: requires intravenous hydration.
e. Mild: 2 to 3 loose stools in 24 hours; Moderate: 4 to 5 loose stools in 24 hours; Severe: 6 or more loose stools in 24 hours.
f. Severity was not collected for use of antipyretic or pain medication.
‡ Eight participants were between 16 and 17 years of age.
* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

Table 3: Study 2 – Frequency and Percentages of Participants with Solicited Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 56 Years of Age and Older – Reactogenicity Subset of the Safety Population*

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=1802 n[b] (%)	Placebo Dose 1 N[a]=1792 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=1660 n[b] (%)	Placebo Dose 2 N[a]=1646 n[b] (%)
Redness[c]				
Any (>2 cm)	85 (4.7)	19 (1.1)	120 (7.2)	12 (0.7)
Mild	55 (3.1)	12 (0.7)	59 (3.6)	8 (0.5)
Moderate	27 (1.5)	5 (0.3)	53 (3.2)	3 (0.2)
Severe	3 (0.2)	2 (0.1)	8 (0.5)	1 (0.1)
Swelling[c]				
Any (>2 cm)	118 (6.5)	21 (1.2)	124 (7.5)	11 (0.7)
Mild	71 (3.9)	10 (0.6)	68 (4.1)	5 (0.3)
Moderate	45 (2.5)	11 (0.6)	53 (3.2)	5 (0.3)
Severe	2 (0.1)	0 (0.0)	3 (0.2)	1 (0.1)
Pain at the injection site[d]				
Any (>2 cm)	1282 (71.1)	166 (9.3)	1098 (66.1)	127 (7.7)
Mild	1008 (55.9)	160 (8.9)	792 (47.7)	125 (7.6)
Moderate	270 (15.0)	6 (0.3)	298 (18.0)	2 (0.1)
Severe	4 (0.2)	0 (0.0)	8 (0.5)	0 (0.0)

Note: Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after vaccination.
a. N = Number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose.
b. n = Number of participants with the specified reaction.
c. Mild: >2.0 to ≤5.0 cm; Moderate: >5.0 to ≤10.0 cm; Severe: >10.0 cm.
d. Mild: does not interfere with activity; Moderate: interferes with activity; Severe: prevents daily activity.
* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

Table 4: Study 2 – Frequency and Percentages of Participants with Solicited Systemic Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 56 Years of Age and Older – Reactogenicity Subset of the Safety Population*

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=1802 n[b] (%)	Placebo Dose 1 N[a]=1792 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=1660 n[b] (%)	Placebo Dose 2 N[a]=1646 n[b] (%)
Fever				
≥38.0°C	26 (1.4)	7 (0.4)	181 (10.9)	4 (0.2)
≥38.0°C to 38.4°C	23 (1.3)	2 (0.1)	131 (7.9)	2 (0.1)
>38.4°C to 38.9°C	1 (0.1)	3 (0.2)	45 (2.7)	1 (0.1)
>38.9°C to 40.0°C	1 (0.1)	2 (0.1)	5 (0.3)	1 (0.1)
>40.0°C	1 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)
Fatigue[c]				
Any	615 (34.1)	405 (22.6)	839 (50.5)	277 (16.8)
Mild	373 (20.7)	252 (14.1)	351 (21.1)	161 (9.8)
Moderate	240 (13.3)	150 (8.4)	442 (26.6)	114 (6.9)
Severe	2 (0.1)	3 (0.2)	46 (2.8)	2 (0.1)

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=1802 n[b] (%)	Placebo Dose 1 N[a]=1792 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=1660 n[b] (%)	Placebo Dose 2 N[a]=1646 n[b] (%)
Headache[c]				
Any	454 (25.2)	325 (18.1)	647 (39.0)	229 (13.9)
Mild	348 (19.3)	242 (13.5)	422 (25.4)	165 (10.0)
Moderate	104 (5.8)	80 (4.5)	216 (13.0)	60 (3.6)
Severe	2 (0.1)	3 (0.2)	9 (0.5)	4 (0.2)
Chills[c]				
Any	113 (6.3)	57 (3.2)	377 (22.7)	46 (2.8)
Mild	87 (4.8)	40 (2.2)	199 (12.0)	35 (2.1)
Moderate	26 (1.4)	16 (0.9)	161 (9.7)	11 (0.7)
Severe	0 (0.0)	1 (0.1)	17 (1.0)	0 (0.0)
Vomiting[d]				
Any	9 (0.5)	9 (0.5)	11 (0.7)	5 (0.3)
Mild	8 (0.4)	9 (0.5)	9 (0.5)	5 (0.3)
Moderate	1 (0.1)	0 (0.0)	1 (0.1)	0 (0.0)
Severe	0 (0.0)	0 (0.0)	1 (0.1)	0 (0.0)
Diarrhea[e]				
Any	147 (8.2)	118 (6.6)	137 (8.3)	99 (6.0)
Mild	118 (6.5)	100 (5.6)	114 (6.9)	73 (4.4)
Moderate	26 (1.4)	17 (0.9)	21 (1.3)	22 (1.3)
Severe	3 (0.2)	1 (0.1)	2 (0.1)	4 (0.2)
New or worsened muscle pain[c]				
Any	251 (13.9)	149 (8.3)	477 (28.7)	87 (5.3)
Mild	168 (9.3)	100 (5.6)	202 (12.2)	57 (3.5)
Moderate	82 (4.6)	46 (2.6)	259 (15.6)	29 (1.8)
Severe	1 (0.1)	3 (0.2)	16 (1.0)	1 (0.1)
New or worsened joint pain[c]				
Any	155 (8.6)	109 (6.1)	313 (18.9)	61 (3.7)
Mild	101 (5.6)	68 (3.8)	161 (9.7)	35 (2.1)
Moderate	52 (2.9)	40 (2.2)	145 (8.7)	25 (1.5)
Severe	2 (0.1)	1 (0.1)	7 (0.4)	1 (0.1)
Use of antipyretic or pain medication	358 (19.9)	213 (11.9)	625 (37.7)	161 (9.8)

Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) from Day 1 to Day 7 after each dose.

a. N = Number of participants reporting at least 1 yes or no response for the specified event after the specified dose.
b. n = Number of participants with the specified reaction.
c. Mild: does not interfere with activity; Moderate: some interference with activity; Severe: prevents daily activity.
d. Mild: 1 to 2 times in 24 hours; Moderate: >2 times in 24 hours; Severe: requires intravenous hydration.
e. Mild: 2 to 3 loose stools in 24 hours; Moderate: 4 to 5 loose stools in 24 hours; Severe: 6 or more loose stools in 24 hours.
* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

From an independent report *(Kamar N, Abravanel F, Marion O, et al. Three doses of an mRNA Covid-19 vaccine in solid-organ transplant recipients. N Engl J Med)*, in 99 individuals who had undergone various solid organ transplant procedures (heart, kidney, liver, lung, pancreas) 97±8 months previously who received a third

vaccine dose, the adverse event profile was similar to that after the second dose and no grade 3 or grade 4 events were reported in recipients who were followed for one month following post Dose 3.

Unsolicited Adverse Events

Serious Adverse Events

In Study 2, among participants 16 through 55 years of age who had received at least 1 dose of vaccine or placebo (Pfizer-BioNTech COVID-19 Vaccine = 10,841; placebo = 10,851), serious adverse events from Dose 1 through up to 30 days after Dose 2 in ongoing follow-up were reported by 0.4% of Pfizer-BioNTech COVID-19 Vaccine recipients and by 0.3% of placebo recipients. In a similar analysis, in participants 56 years of age and older (Pfizer-BioNTech COVID-19 Vaccine = 7,960, placebo = 7,934), serious adverse events were reported by 0.8% of Pfizer-BioNTech COVID-19 Vaccine recipients and by 0.6% of placebo recipients who received at least 1 dose of Pfizer-BioNTech COVID-19 Vaccine or placebo, respectively. In these analyses, 91.6% of study participants had at least 30 days of follow-up after Dose 2.

Appendicitis was reported as a serious adverse event for 12 participants, and numerically higher in the vaccine group, 8 vaccine participants and 4 placebo participants. Currently available information is insufficient to determine a causal relationship with the vaccine. There were no other notable patterns or numerical imbalances between treatment groups for specific categories of serious adverse events (including neurologic, neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to Pfizer-BioNTech COVID-19 Vaccine.

Non-Serious Adverse Events

In Study 2 in which 10,841 participants 16 through 55 years of age received Pfizer-BioNTech COVID-19 Vaccine and 10,851 participants received placebo, non-serious adverse events from Dose 1 through up to 30 days after Dose 2 in ongoing follow-up were reported in 29.3% of participants who received Pfizer-BioNTech COVID-19 Vaccine and 13.2% of participants in the placebo group, for participants who received at least 1 dose. Overall in a similar analysis in which 7960 participants 56 years of age and older received Pfizer-BioNTech COVID-19 Vaccine, non-serious adverse events within 30 days were reported in 23.8% of participants who received Pfizer-BioNTech COVID-19 Vaccine and 11.7% of participants in the placebo group, for participants who received at least 1 dose. In these analyses, 91.6% of study participants had at least 30 days of follow-up after Dose 2.

The higher frequency of reported unsolicited non-serious adverse events among Pfizer-BioNTech COVID-19 Vaccine recipients compared to placebo recipients was primarily attributed to local and systemic adverse events reported during the first 7 days following vaccination that are consistent with adverse reactions solicited among participants in the reactogenicity subset and presented in Tables 3 and 4. From Dose 1 through 30 days after Dose 2, reports of lymphadenopathy were imbalanced with notably more cases in the Pfizer-BioNTech COVID-19 Vaccine group (64) vs. the placebo group (6), which is plausibly related to vaccination. Throughout the safety follow-up period to date, Bell's palsy (facial paralysis) was reported by four participants in the Pfizer-BioNTech COVID-19 Vaccine group. Onset of facial paralysis was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of Bell's palsy were reported in the placebo group. Currently available information is insufficient to determine a causal relationship with the vaccine. There were no other notable patterns or numerical imbalances between treatment groups for specific categories of non-serious adverse events (including other neurologic or neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to Pfizer-BioNTech COVID-19 Vaccine.

Adolescents 12 Through 15 Years of Age

In an analysis of Study 2, based on data up to the cutoff date of March 13, 2021, 2,260 adolescents (1,131 Pfizer-BioNTech COVID-19 Vaccine; 1,129 placebo) were 12 through 15 years of age. Of these, 1,308 (660 Pfizer-BioNTech COVID-19 Vaccine and 648 placebo) adolescents have been followed for at least 2 months after the second dose of Pfizer-BioNTech COVID-19 Vaccine. The safety evaluation in Study 2 is ongoing.

Demographic characteristics in Study 2 were generally similar with regard to age, gender, race, and ethnicity among adolescents who received Pfizer-BioNTech COVID-19 Vaccine and those who received placebo. Overall, among the adolescents who received the Pfizer-BioNTech COVID-19 Vaccine, 50.1% were male and 49.9% were female, 85.9% were White, 4.6% were Black or African American, 11.7% were Hispanic/Latino, 6.4% were Asian, and 0.4% were American Indian/Alaska Native.

Solicited Local and Systemic Adverse Reactions

The mean duration of pain at the injection site after Dose 1 was 2.4 days (range 1 to 10 days), for redness 2.4 days (range 1 to 16 days), and for swelling 1.9 days (range 1 to 5 days) for adolescents in the Pfizer-BioNTech COVID-19 Vaccine group.

Table 5: Study 2 – Frequency and Percentages of Adolescents With Solicited Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Adolescents 12 Through 15 Years of Age – Safety Population*

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=1127 n[b] (%)	Placebo Dose 1 N[a]=1127 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=1097 n[b] (%)	Placebo Dose 2 N[a]=1078 n[b] (%)
Redness[c]				
Any (>2 cm)	65 (5.8)	12 (1.1)	55 (5.0)	10 (0.9)
Mild	44 (3.9)	11 (1.0)	29 (2.6)	8 (0.7)
Moderate	20 (1.8)	1 (0.1)	26 (2.4)	2 (0.2)
Severe	1 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)
Swelling[c]				
Any (>2 cm)	78 (6.9)	11 (1.0)	54 (4.9)	6 (0.6)
Mild	55 (4.9)	9 (0.8)	36 (3.3)	4 (0.4)
Moderate	23 (2.0)	2 (0.2)	18 (1.6)	2 (0.2)
Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pain at the injection site[d]				
Any	971 (86.2)	263 (23.3)	866 (78.9)	193 (17.9)
Mild	467 (41.4)	227 (20.1)	466 (42.5)	164 (15.2)
Moderate	493 (43.7)	36 (3.2)	393 (35.8)	29 (2.7)
Severe	11 (1.0)	0 (0.0)	7 (0.6)	0 (0.0)

Note: Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after vaccination.
a. N = Number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose.
b. n = Number of participants with the specified reaction.
c. Mild: >2.0 to ≤5.0 cm; Moderate: >5.0 to ≤10.0 cm; Severe: >10.0 cm.
d. Mild: does not interfere with activity; Moderate: interferes with activity; Severe: prevents daily activity.
* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

Table 6: Study 2 – Frequency and Percentages of Adolescents with Solicited Systemic Reactions, by Maximum Severity, Within 7 Days After Each Dose – Adolescents 12 Through 15 Years of Age – Safety Population*

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=1127 n[b] (%)	Placebo Dose 1 N[a]=1127 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=1097 n[b] (%)	Placebo Dose 2 N[a]=1078 n[b] (%)
Fever				
≥38.0°C	114 (10.1)	12 (1.1)	215 (19.6)	7 (0.6)
≥38.0°C to 38.4°C	74 (6.6)	8 (0.7)	107 (9.8)	5 (0.5)
>38.4°C to 38.9°C	29 (2.6)	2 (0.2)	83 (7.6)	1 (0.1)
>38.9°C to 40.0°C	10 (0.9)	2 (0.2)	25 (2.3)	1 (0.1)
>40.0°C	1 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)
Fatigue[c]				
Any	677 (60.1)	457 (40.6)	726 (66.2)	264 (24.5)
Mild	278 (24.7)	250 (22.2)	232 (21.1)	133 (12.3)
Moderate	384 (34.1)	199 (17.7)	468 (42.7)	127 (11.8)
Severe	15 (1.3)	8 (0.7)	26 (2.4)	4 (0.4)
Headache[c]				
Any	623 (55.3)	396 (35.1)	708 (64.5)	263 (24.4)
Mild	361 (32.0)	256 (22.7)	302 (27.5)	169 (15.7)
Moderate	251 (22.3)	131 (11.6)	384 (35.0)	93 (8.6)
Severe	11 (1.0)	9 (0.8)	22 (2.0)	1 (0.1)
Chills[c]				
Any	311 (27.6)	109 (9.7)	455 (41.5)	73 (6.8)
Mild	195 (17.3)	82 (7.3)	221 (20.1)	52 (4.8)
Moderate	111 (9.8)	25 (2.2)	214 (19.5)	21 (1.9)
Severe	5 (0.4)	2 (0.2)	20 (1.8)	0 (0.0)
Vomiting[d]				
Any	31 (2.8)	10 (0.9)	29 (2.6)	12 (1.1)
Mild	30 (2.7)	8 (0.7)	25 (2.3)	11 (1.0)
Moderate	0 (0.0)	2 (0.2)	4 (0.4)	1 (0.1)
Severe	1 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)
Diarrhea[e]				
Any	90 (8.0)	82 (7.3)	65 (5.9)	43 (4.0)
Mild	77 (6.8)	72 (6.4)	59 (5.4)	38 (3.5)
Moderate	13 (1.2)	10 (0.9)	6 (0.5)	5 (0.5)
Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
New or worsened muscle pain[c]				
Any	272 (24.1)	148 (13.1)	355 (32.4)	90 (8.3)
Mild	125 (11.1)	88 (7.8)	152 (13.9)	51 (4.7)
Moderate	145 (12.9)	60 (5.3)	197 (18.0)	37 (3.4)
Severe	2 (0.2)	0 (0.0)	6 (0.5)	2 (0.2)

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=1127 n[b] (%)	Placebo Dose 1 N[a]=1127 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=1097 n[b] (%)	Placebo Dose 2 N[a]=1078 n[b] (%)
New or worsened joint pain[c]				
Any	109 (9.7)	77 (6.8)	173 (15.8)	51 (4.7)
Mild	66 (5.9)	50 (4.4)	91 (8.3)	30 (2.8)
Moderate	42 (3.7)	27 (2.4)	78 (7.1)	21 (1.9)
Severe	1 (0.1)	0 (0.0)	4 (0.4)	0 (0.0)
Use of antipyretic or pain medication[f]	413 (36.6)	111 (9.8)	557 (50.8)	95 (8.8)

Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) from Day 1 to Day 7 after each dose.

a. N = Number of participants reporting at least 1 yes or no response for the specified event after the specified dose.
b. n = Number of participants with the specified reaction.
c. Mild: does not interfere with activity; Moderate: some interference with activity; Severe: prevents daily activity.
d. Mild: 1 to 2 times in 24 hours; Moderate: >2 times in 24 hours; Severe: requires intravenous hydration.
e. Mild: 2 to 3 loose stools in 24 hours; Moderate: 4 to 5 loose stools in 24 hours; Severe: 6 or more loose stools in 24 hours.
f. Severity was not collected for use of antipyretic or pain medication.
* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

Unsolicited Adverse Events

In the following analyses of Study 2 in adolescents 12 through 15 years of age (1,131 of whom received Pfizer-BioNTech COVID-19 Vaccine and 1,129 of whom received placebo), 98.3% of study participants had at least 30 days of follow-up after Dose 2.

Serious Adverse Events

Serious adverse events from Dose 1 through up to 30 days after Dose 2 in ongoing follow-up were reported by 0.4% of Pfizer-BioNTech COVID-19 Vaccine recipients and by 0.1% of placebo recipients. There were no notable patterns or numerical imbalances between treatment groups for specific categories of serious adverse events that would suggest a causal relationship to Pfizer-BioNTech COVID-19 Vaccine.

Non-Serious Adverse Events

Non-serious adverse events from Dose 1 through up to 30 days after Dose 2 in ongoing follow-up were reported by 5.8% of Pfizer-BioNTech COVID-19 Vaccine recipients and by 5.8% of placebo recipients. From Dose 1 through 30 days after Dose 2, reports of lymphadenopathy plausibly related to the study intervention were imbalanced, with notably more cases in the Pfizer-BioNTech COVID-19 Vaccine group (7) vs. the placebo group (1). There were no other notable patterns or numerical imbalances between treatment groups for specific categories of non-serious adverse events that would suggest a causal relationship to Pfizer-BioNTech COVID-19 Vaccine.

Booster Dose

A subset of Study 2 Phase 2/3 participants of 306 adults 18 through 55 years of age received a booster dose of Pfizer-BioNTech COVID-19 Vaccine approximately 6 months (range of 4.8 to 8.0 months) after completing the primary series. Additionally, a total of 23 Study 2 Phase 1 participants (11 participants 18 through 55 years of age and 12 participants 65 through 85 years of age) received a booster dose of Pfizer-BioNTech COVID-19

Vaccine approximately 8 months (range 7.9 to 8.8 months) after completing the primary series. Safety monitoring after the booster dose was the same as that in the reactogenicity subset who received the primary series.

Among the 306 Phase 2/3 participants, the median age was 42 years (range 19 through 55 years of age), 45.8% were male and 54.2% were female, 81.4% were White, 27.8% were Hispanic/Latino, 9.2% were Black or African American, 5.2% were Asian, and 0.7% were American Indian/Alaska Native. Among the 12 Phase 1 participants 65 through 85 years of age, the median age was 69 years (range 65 through 75 years of age), 6 were male and all were White and Not Hispanic/Latino. Following the booster dose, the median follow-up time was 2.6 months (range 2.1 to 2.9 months) for Phase 1 participants and 2.6 months (range 1.1 to 2.8 months) for Phase 2/3 participants.

Solicited Local and Systemic Adverse Reactions

Table 7 and Table 8 present the frequency and severity of reported solicited local and systemic reactions, respectively, within 7 days of a booster dose of Pfizer-BioNTech COVID-19 Vaccine for Phase 2/3 participants 18 through 55 years of age.

In participants who received a booster dose, the mean duration of pain at the injection site after the booster dose was 2.6 days (range 1 to 8 days), for redness 2.2 days (range 1 to 15 days), and for swelling 2.2 days (range 1 to 8 days).

Table 7: Study 2 – Frequency and Percentages of Participants With Solicited Local Reactions, By Maximum Severity, Within 7 Days After the Booster Dose of Pfizer-BioNTech COVID-19 Vaccine – Participants 18 through 55 Years of Age*

Solicited Local Reaction	Pfizer-BioNTech COVID-19 Vaccine Booster Dose N[a] = 289 n[b] (%)
Redness[c]	
Any (>2 cm)	17 (5.9)
Mild	10 (3.5)
Moderate	7 (2.4)
Severe	0
Swelling[c]	
Any (>2 cm)	23 (8.0)
Mild	13 (4.5)
Moderate	9 (3.1)
Severe	1 (0.3)

Solicited Local Reaction	Pfizer-BioNTech COVID-19 Vaccine Booster Dose N[a] = 289 n[b] (%)
Pain at the injection site[d]	
Any	240 (83.0)
Mild	174 (60.2)
Moderate	65 (22.5)
Severe	1 (0.3)

Note: Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after the booster dose.
Note: No Grade 4 solicited local reactions were reported.
* A subset of Phase 2/3 participants 18 through 55 years of age who received a booster dose of COMIRNATY approximately 6 months after completing the primary series.
a. N = Number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose.
b. n = Number of participants with the specified reaction.
c. Mild: >2.0 to 5.0 cm; Moderate: >5.0 to 10.0 cm; Severe: >10.0 cm.
d. Mild: does not interfere with activity; Moderate: interferes with activity; Severe: prevents daily activity.

Table 8: Study 2 – Frequency and Percentages of Participants With Solicited Systemic Reactions, by Maximum Severity, Within 7 Days After the Booster Dose of Pfizer-BioNTech COVID-19 Vaccine – Participants 18 through 55 Years of Age*

Solicited Systemic Reaction	Pfizer-BioNTech COVID-19 Vaccine Booster Dose N[a] = 289 n[b] (%)
Fever	
≥38.0°C	25 (8.7)
≥38.0°C to 38.4°C	12 (4.2)
>38.4°C to 38.9°C	12 (4.2)
>38.9°C to 40.0°C	1 (0.3)
>40.0°C	0
Fatigue[c]	
Any	184 (63.7)
Mild	68 (23.5)
Moderate	103 (35.6)
Severe	13 (4.5)
Headache[c]	
Any	140 (48.4)
Mild	83 (28.7)
Moderate	54 (18.7)
Severe	3 (1.0)
Chills[c]	
Any	84 (29.1)
Mild	37 (12.8)
Moderate	44 (15.2)
Severe	3 (1.0)
Vomiting[d]	
Any	5 (1.7)
Mild	5 (1.7)
Moderate	0
Severe	0

Solicited Systemic Reaction	Pfizer-BioNTech COVID-19 Vaccine Booster Dose N[a] = 289 n[b] (%)
Diarrhea[e]	
Any	25 (8.7)
Mild	21 (7.3)
Moderate	4 (1.4)
Severe	0
New or worsened muscle pain[c]	
Any	113 (39.1)
Mild	52 (18.0)
Moderate	57 (19.7)
Severe	4 (1.4)
New or worsened joint pain[c]	
Any	73 (25.3)
Mild	36 (12.5)
Moderate	36 (12.5)
Severe	1 (0.3)
Use of antipyretic or pain medication[f]	135 (46.7)

Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) from Day 1 to Day 7 after the booster dose.

Note: No Grade 4 solicited systemic reactions were reported.

* A subset of Phase 2/3 participants 18 through 55 years of age who received a booster dose of COMIRNATY approximately 6 months after completing the primary series.

a. N = Number of participants reporting at least 1 yes or no response for the specified event after the specified dose.
b. n = Number of participants with the specified reaction.
c. Mild: does not interfere with activity; Moderate: some interference with activity; Severe: prevents daily activity.
d. Mild: 1 to 2 times in 24 hours; Moderate: >2 times in 24 hours; Severe: requires intravenous hydration.
e. Mild: 2 to 3 loose stools in 24 hours; Moderate: 4 to 5 loose stools in 24 hours; Severe: 6 or more loose stools in 24 hours.
f. Severity was not collected for use of antipyretic or pain medication.

In Phase 1 participants ≥65 years of age (n = 12), local reaction pain at the injection site (n = 8, 66.7%) and systemic reactions fatigue (n = 5, 41.7%), headache (n = 5, 41.7%), chills (n = 2, 16.7%), muscle pain (n = 4, 33.3%), and joint pain (n = 2, 16.7%) were reported after the booster dose. No participant in this age group reported a severe systemic event or fever after the booster dose.

Unsolicited Adverse Events

Overall, the 306 participants who received a booster dose, had a median follow-up time of 2.6 months after the booster dose to the cut-off date (June 17, 2021).

In an analysis of all unsolicited adverse events reported following the booster dose, through 1 month after the booster dose, in participants 18 through 55 years of age (N = 306), those assessed as adverse reactions not already captured by solicited local and systemic reactions were lymphadenopathy (n = 16, 5.2%), nausea (n = 2, 0.7%), decreased appetite (n = 1, 0.3%), rash (n = 1, 0.3%), and pain in extremity (n = 1, 0.3%).

Serious Adverse Events

Of the 306 participants who received a booster dose of Pfizer-BioNTech COVID-19 Vaccine, there were no serious adverse events reported from the booster dose through 30 days after the booster dose. One participant reported a serious adverse event 61 days after the booster dose that was assessed as unrelated to vaccination.

6.2 Post Authorization Experience

The following adverse reactions have been identified during post authorization use of Pfizer-BioNTech COVID-19 Vaccine. Because these reactions are reported voluntarily, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure.

Cardiac Disorders: myocarditis, pericarditis
Gastrointestinal Disorders: diarrhea, vomiting
Immune System Disorders: severe allergic reactions, including anaphylaxis, and other hypersensitivity reactions (e.g., rash, pruritus, urticaria, angioedema)
Musculoskeletal and Connective Tissue Disorders: pain in extremity (arm)
Nervous System Disorders: syncope

8 REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS[7]

See Overall Safety Summary (Section 6) for additional information.

The vaccination provider enrolled in the federal COVID-19 Vaccination Program is responsible for MANDATORY reporting of the listed events following Pfizer-BioNTech COVID-19 Vaccine to the Vaccine Adverse Event Reporting System (VAERS):

- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events* (irrespective of attribution to vaccination)
- Cases of Multisystem Inflammatory Syndrome (MIS) in children and adults
- Cases of COVID-19 that result in hospitalization or death

*Serious adverse events are defined as:

- Death
- A life-threatening adverse event
- Inpatient hospitalization or prolongation of existing hospitalization
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
- A congenital anomaly/birth defect
- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above

Instructions for Reporting to VAERS

The vaccination provider enrolled in the federal COVID-19 Vaccination Program should complete and submit a VAERS form to FDA using one of the following methods:

- Complete and submit the report online: https://vaers.hhs.gov/reportevent.html, or
- If you are unable to submit this form electronically, you may fax it to VAERS at 1-877-721-0366. If you need additional help submitting a report you may call the VAERS toll-free information line at 1-800-822-7967 or send an email to info@vaers.org.

[7] Vaccination providers administering COMIRNATY (COVID-19 Vaccine, mRNA) must adhere to the same reporting requirements.

IMPORTANT: When reporting adverse events or vaccine administration errors to VAERS, please complete the entire form with detailed information. It is important that the information reported to FDA be as detailed and complete as possible. Information to include:

- Patient demographics (e.g., patient name, date of birth)
- Pertinent medical history
- Pertinent details regarding admission and course of illness
- Concomitant medications
- Timing of adverse event(s) in relationship to administration of the Pfizer-BioNTech COVID-19 Vaccine
- Pertinent laboratory and virology information
- Outcome of the event and any additional follow-up information if it is available at the time of the VAERS report. Subsequent reporting of follow-up information should be completed if additional details become available.

The following steps are highlighted to provide the necessary information for safety tracking:

1. In Box 17, provide information on Pfizer-BioNTech COVID-19 Vaccine and any other vaccines administered on the same day; and in Box 22, provide information on any other vaccines received within one month prior.
2. In Box 18, description of the event:
    a. Write "Pfizer-BioNTech COVID-19 Vaccine EUA" as the first line.
    b. Provide a detailed report of vaccine administration error and/or adverse event. It is important to provide detailed information regarding the patient and adverse event/medication error for ongoing safety evaluation of this unapproved vaccine. Please see information to include listed above.
3. Contact information:
    a. In Box 13, provide the name and contact information of the prescribing healthcare provider or institutional designee who is responsible for the report.
    b. In Box 14, provide the name and contact information of the best doctor/healthcare professional to contact about the adverse event.
    c. In Box 15, provide the address of the facility where vaccine was given (NOT the healthcare provider's office address).

Other Reporting Instructions

Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.

To the extent feasible, report adverse events to Pfizer Inc. using the contact information below or by providing a copy of the VAERS form to Pfizer Inc.

Website	Fax number	Telephone number
www.pfizersafetyreporting.com	1-866-635-8337	1-800-438-1985

10 DRUG INTERACTIONS

There are no data to assess the concomitant administration of the Pfizer-BioNTech COVID-19 Vaccine with other vaccines.

11 USE IN SPECIFIC POPULATIONS

11.1 Pregnancy

Risk Summary

All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively. Available data on Pfizer-BioNTech COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.

In a reproductive and developmental toxicity study, 0.06 mL of a vaccine formulation containing the same quantity of nucleoside-modified messenger ribonucleic acid (mRNA) (30 mcg) and other ingredients included in a single human dose of Pfizer-BioNTech COVID-19 Vaccine was administered to female rats by the intramuscular route on four occasions: 21 and 14 days prior to mating, and on gestation days 9 and 20. No vaccine-related adverse effects on female fertility, fetal development, or postnatal development were reported in the study.

11.2 Lactation

Risk Summary

Data are not available to assess the effects of Pfizer-BioNTech COVID-19 Vaccine on the breastfed infant or on milk production/excretion.

11.3 Pediatric Use

Emergency Use Authorization of Pfizer-BioNTech COVID-19 Vaccine in adolescents 12 through 17 years of age is based on safety and effectiveness data in this age group and in adults.

Emergency Use Authorization of Pfizer-BioNTech COVID-19 Vaccine does not include use in individuals younger than 12 years of age.

11.4 Geriatric Use

Clinical studies of Pfizer-BioNTech COVID-19 Vaccine include participants 65 years of age and older who received the primary series and their data contributes to the overall assessment of safety and efficacy *[see Overall Safety Summary (6.1) and Clinical Trial Results and Supporting Data for EUA (18.1)]*. Of the total number of Pfizer-BioNTech COVID-19 Vaccine recipients in Study 2 (N=20,033), 21.4% (n=4,294) were 65 years of age and older and 4.3% (n=860) were 75 years of age and older.

The safety of a booster dose of Pfizer-BioNTech COVID-19 Vaccine in individuals 65 years of age and older is based on safety data in 12 booster dose recipients 65 through 85 years of age and 306 booster dose recipients 18 through 55 years of age in Study 2. The effectiveness of a booster dose of Pfizer-BioNTech COVID-19 Vaccine in individuals 65 years of age and older is based on effectiveness data in 306 booster dose recipients 18 through 55 years of age in Study 2.

11.5 Use in Immunocompromised

From an independent report *(Kamar N, Abravanel F, Marion O, et al. Three doses of an mRNA Covid-19 vaccine in solid-organ transplant recipients. N Engl J Med)*, safety and effectiveness of a third dose of the

Pfizer-BioNTech COVID-19 vaccine have been evaluated in persons that received solid organ transplants. The administration of a third dose of vaccine appears to be only moderately effective in increasing potentially protective antibody titers. Patients should still be counselled to maintain physical precautions to help prevent COVID-19. In addition, close contacts of immunocompromised persons should be vaccinated as appropriate for their health status.

13 DESCRIPTION

The Pfizer-BioNTech COVID-19 Vaccine is supplied as a frozen suspension in multiple dose vials; each vial must be diluted with 1.8 mL of sterile 0.9% Sodium Chloride Injection, USP prior to use to form the vaccine. Each dose of the Pfizer-BioNTech COVID-19 Vaccine contains 30 mcg of a nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2.

Each dose of the Pfizer-BioNTech COVID-19 Vaccine also includes the following ingredients: lipids (0.43 mg (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.05 mg 2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 0.09 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.2 mg cholesterol), 0.01 mg potassium chloride, 0.01 mg monobasic potassium phosphate, 0.36 mg sodium chloride, 0.07 mg dibasic sodium phosphate dihydrate, and 6 mg sucrose. The diluent (0.9% Sodium Chloride Injection, USP) contributes an additional 2.16 mg sodium chloride per dose.

The Pfizer-BioNTech COVID-19 Vaccine does not contain preservative. The vial stoppers are not made with natural rubber latex.

14 CLINICAL PHARMACOLOGY

14.1 Mechanism of Action

The modRNA in the Pfizer-BioNTech COVID-19 Vaccine is formulated in lipid particles, which enable delivery of the RNA into host cells to allow expression of the SARS-CoV-2 S antigen. The vaccine elicits an immune response to the S antigen, which protects against COVID-19.

18 CLINICAL TRIAL RESULTS AND SUPPORTING DATA FOR EUA

18.1 Efficacy of Primary Series in Participants 16 Years of Age and Older

Study 2 is a multicenter, multinational, Phase 1/2/3, randomized, placebo-controlled, observer-blind, dose-finding, vaccine candidate-selection, and efficacy study in participants 12 years of age and older. Randomization was stratified by age: 12 through 15 years of age, 16 through 55 years of age, or 56 years of age and older, with a minimum of 40% of participants in the ≥56-year stratum. The study excluded participants who were immunocompromised and those who had previous clinical or microbiological diagnosis of COVID-19. Participants with preexisting stable disease, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 6 weeks before enrollment, were included as were participants with known stable infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV).

In the Phase 2/3 portion of Study 2, based on data accrued through November 14, 2020, approximately 44,000 participants 12 years of age and older were randomized equally and received 2 doses of Pfizer-BioNTech COVID-19 Vaccine or placebo separated by 21 days. Participants are planned to be followed for up to 24 months, for assessments of safety and efficacy against COVID-19.

The population for the analysis of the primary efficacy endpoint included, 36,621 participants 12 years of age and older (18,242 in the Pfizer-BioNTech COVID-19 Vaccine group and 18,379 in the placebo group) who did not have evidence of prior infection with SARS-CoV-2 through 7 days after the second dose. Table 9 presents the specific demographic characteristics in the studied population.

Table 9: Demographics (population for the primary efficacy endpoint)[a]

	Pfizer-BioNTech COVID-19 Vaccine (N=18,242) n (%)	Placebo (N=18,379) n (%)
Sex		
Male	9318 (51.1)	9225 (50.2)
Female	8924 (48.9)	9154 (49.8)
Age (years)		
Mean (SD)	50.6 (15.70)	50.4 (15.81)
Median	52.0	52.0
Min, max	(12, 89)	(12, 91)
Age group		
≥12 through 15 years[b]	46 (0.3)	42 (0.2)
≥16 through 17 years	66 (0.4)	68 (0.4)
≥16 through 64 years	14,216 (77.9)	14,299 (77.8)
≥65 through 74 years	3176 (17.4)	3226 (17.6)
≥75 years	804 (4.4)	812 (4.4)
Race		
White	15,110 (82.8)	15,301 (83.3)
Black or African American	1617 (8.9)	1617 (8.8)
American Indian or Alaska Native	118 (0.6)	106 (0.6)
Asian	815 (4.5)	810 (4.4)
Native Hawaiian or other Pacific Islander	48 (0.3)	29 (0.2)
Other[c]	534 (2.9)	516 (2.8)
Ethnicity		
Hispanic or Latino	4886 (26.8)	4857 (26.4)
Not Hispanic or Latino	13,253 (72.7)	13,412 (73.0)
Not reported	103 (0.6)	110 (0.6)
Comorbidities[d]		
Yes	8432 (46.2)	8450 (46.0)
No	9810 (53.8)	9929 (54.0)

a. All eligible randomized participants who receive all vaccination(s) as randomized within the predefined window, have no other important protocol deviations as determined by the clinician, and have no evidence of SARS-CoV-2 infection prior to 7 days after Dose 2.

b. 100 participants 12 through 15 years of age with limited follow-up in the randomized population received at least one dose (49 in the vaccine group and 51 in the placebo group). Some of these participants were included in the efficacy evaluation depending on the population analyzed. They contributed to exposure information but with no confirmed COVID-19 cases, and did not affect efficacy conclusions.

c. Includes multiracial and not reported.

d. Number of participants who have 1 or more comorbidities that increase the risk of severe COVID-19 disease
- Chronic lung disease (e.g., emphysema and chronic bronchitis, idiopathic pulmonary fibrosis, and cystic fibrosis) or moderate to severe asthma
- Significant cardiac disease (e.g., heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)
- Obesity (body mass index ≥30 kg/m^2)
- Diabetes (Type 1, Type 2 or gestational)

	Pfizer-BioNTech COVID-19 Vaccine (N=18,242) n (%)	Placebo (N=18,379) n (%)

- Liver disease
- Human Immunodeficiency Virus (HIV) infection (not included in the efficacy evaluation)

The population in the primary efficacy analysis included all participants 12 years of age and older who had been enrolled from July 27, 2020, and followed for the development of COVID-19 through November 14, 2020. Participants 18 through 55 years of age and 56 years of age and older began enrollment from July 27, 2020, 16 through 17 years of age began enrollment from September 16, 2020, and 12 through 15 years of age began enrollment from October 15, 2020.

The vaccine efficacy information is presented in Table 10.

Table 10: Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Age Subgroup – Participants Without Evidence of Infection and Participants With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

First COVID-19 occurrence from 7 days after Dose 2 in participants without evidence of prior SARS-CoV-2 infection*			
Subgroup	Pfizer-BioNTech COVID-19 Vaccine N[a]=18,198 Cases n1[b] Surveillance Time[c] (n2[d])	Placebo N[a]=18,325 Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy % (95% CI)
All subjects[e]	8 2.214 (17,411)	162 2.222 (17,511)	95.0 (90.3, 97.6)[f]
16 through 64 years	7 1.706 (13,549)	143 1.710 (13,618)	95.1 (89.6, 98.1)[g]
65 years and older	1 0.508 (3848)	19 0.511 (3880)	94.7 (66.7, 99.9)[g]
First COVID-19 occurrence from 7 days after Dose 2 in participants with or without evidence of prior SARS-CoV-2 infection			
Subgroup	Pfizer-BioNTech COVID-19 Vaccine N[a]=19,965 Cases n1[b] Surveillance Time[c] (n2[d])	Placebo N[a]=20,172 Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy % (95% CI)
All subjects[e]	9 2.332 (18,559)	169 2.345 (18,708)	94.6 (89.9, 97.3)[f]
16 through 64 years	8 1.802 (14,501)	150 1.814 (14,627)	94.6 (89.1, 97.7)[g]
65 years and older	1 0.530 (4044)	19 0.532 (4067)	94.7 (66.8, 99.9)[g]

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting).

* Participants who had no evidence of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

a. N = Number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of participants at risk for the endpoint.
e. No confirmed cases were identified in adolescents 12 through 15 years of age.
f. Credible interval for vaccine efficacy (VE) was calculated using a beta-binomial model with a beta (0.700102, 1) prior for θ=r(1-VE)/(1+r(1-VE)), where r is the ratio of surveillance time in the active vaccine group over that in the placebo group.
g. Confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted to the surveillance time.

18.2 Efficacy of Primary Series in Adolescents 12 Through 15 Years of Age

A descriptive efficacy analysis of Study 2 has been performed in approximately 2,200 adolescents 12 through 15 years of age evaluating confirmed COVID-19 cases accrued up to a data cutoff date of March 13, 2021.

The efficacy information in adolescents 12 through 15 years of age is presented in Table 11.

Table 11: Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2: Without Evidence of Infection and With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period, Adolescents 12 Through 15 Years of Age Evaluable Efficacy (7 Days) Population

First COVID-19 occurrence from 7 days after Dose 2 in adolescents 12 through 15 years of age without evidence of prior SARS-CoV-2 infection*			
	Pfizer-BioNTech COVID-19 Vaccine N[a]=1005 Cases n1[b] Surveillance Time[c] (n2[d])	Placebo N[a]=978 Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy % (95% CI[e])
Adolescents 12 through 15 years of age	0 0.154 (1001)	16 0.147 (972)	100.0 (75.3, 100.0)
First COVID-19 occurrence from 7 days after Dose 2 in adolescents 12 through 15 years of age with or without evidence of prior SARS-CoV-2 infection			
	Pfizer-BioNTech COVID-19 Vaccine N[a]=1119 Cases n1[b] Surveillance Time[c] (n2[d])	Placebo N[a]=1110 Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy % (95% CI[e])
Adolescents 12 through 15 years of age	0 0.170 (1109)	18 0.163 (1094)	100.0 (78.1, 100.0)

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting).

* Participants who had no evidence of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

a. N = Number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of participants at risk for the endpoint.
e. Confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted for surveillance time.

18.3 Immunogenicity of Primary Series in Adolescents 12 Through 15 Years of Age

In Study 2, an analysis of SARS-CoV-2 50% neutralizing titers 1 month after Dose 2 in a randomly selected subset of participants demonstrated non-inferior immune responses (within 1.5-fold) comparing adolescents 12 through 15 years of age to participants 16 through 25 years of age who had no serological or virological evidence of past SARS-CoV-2 infection up to 1 month after Dose 2 (Table 12).

Table 12: Summary of Geometric Mean Ratio for 50% Neutralizing Titer – Comparison of Adolescents 12 Through 15 Years of Age to Participants 16 Through 25 Years of Age (Immunogenicity Subset) –Participants Without Evidence of Infection up to 1 Month After Dose 2 – Dose 2 Evaluable Immunogenicity Population

		Pfizer-BioNTech COVID-19 Vaccine			
		12 Through 15 Years n[a]=190	16 Through 25 Years n[a]=170	12 Through 15 Years/ 16 Through 25 Years	
Assay	Time Point[b]	GMT[c] (95% CI[c])	GMT[c] (95% CI[c])	GMR[d] (95% CI[d])	Met Noninferiority Objective[e] (Y/N)
SARS-CoV-2 neutralization assay - NT50 (titer)[f]	1 month after Dose 2	1239.5 (1095.5, 1402.5)	705.1 (621.4, 800.2)	1.76 (1.47, 2.10)	Y

Abbreviations: CI = confidence interval; GMR = geometric mean ratio; GMT = geometric mean titer; LLOQ = lower limit of quantitation; NAAT = nucleic-acid amplification test; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

Note: Participants who had no serological or virological evidence (up to 1 month after receipt of the last dose) of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit up to 1 month after Dose 2 were included in the analysis.

a. n = Number of participants with valid and determinate assay results for the specified assay at the given dose/sampling time point.
b. Protocol-specified timing for blood sample collection.
c. GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
d. GMRs and 2-sided 95% CIs were calculated by exponentiating the mean difference of the logarithms of the titers (Group 1 [12 through 15 years of age] – Group 2 [16 through 25 years of age]) and the corresponding CI (based on the Student t distribution).
e. Noninferiority is declared if the lower bound of the 2-sided 95% CI for the GMR is greater than 0.67.
f. SARS-CoV-2 50% neutralization titers (NT50) were determined using the SARS-CoV-2 mNeonGreen Virus Microneutralization Assay. The assay uses a fluorescent reporter virus derived from the USA_WA1/2020 strain and virus neutralization is read on Vero cell monolayers. The sample NT50 is defined as the reciprocal serum dilution at which 50% of the virus is neutralized.

18.4 Immunogenicity of Booster Dose in Participants 18 Through 55 Years of Age

Effectiveness of a booster dose of Pfizer-BioNTech COVID-19 Vaccine was based on an assessment of 50% neutralizing antibody titers (NT50) against SARS-CoV-2 (USA_WA1/2020). In Study 2, analyses of NT50 1 month after the booster dose compared to 1 month after the primary series in individuals 18 through 55 years of age who had no serological or virological evidence of past SARS-CoV-2 infection up to 1 month after the booster vaccination demonstrated noninferiority for both geometric mean ratio (GMR) and difference in seroresponse rates. Seroresponse for a participant was defined as achieving a ≥4-fold rise in NT50 from baseline (before primary series). These analyses are summarized in Table 13 and Table 14.

Table 13: Geometric Mean 50% Neutralizing Titer (SARS-CoV-2 USA_WA1/2020) – Comparison of 1 Month After Booster Dose to 1 Month After Primary Series – Participants 18 Through 55 Years of Age Without Evidence of Infection up to 1 Month After Booster Dose* – Booster Dose Evaluable Immunogenicity Population±

Assay	n[a]	1 Month After Booster Dose GMT[b] (95% CI[b])	1 Month After Primary Series GMT[b] (95% CI[b])	1 Month After Booster Dose/ 1 Month After Primary Series GMR[c] (97.5% CI[c])	Met Noninferiority Objective[d] (Y/N)
SARS-CoV-2 neutralization assay - NT50 (titer)[e]	212	2466.0 (2202.6, 2760.8)	750.6 (656.2, 858.6)	3.29 (2.77, 3.90)	Y

Abbreviations: CI = confidence interval; GMR = geometric mean ratio; GMT = geometric mean titer; LLOQ = lower limit of quantitation; N-binding = SARS-CoV-2 nucleoprotein-binding; NAAT = nucleic acid amplification test; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; Y/N = yes/no.

* Participants who had no serological or virological evidence (up to 1 month after receipt of a booster dose of Pfizer-BioNTech COVID-19 Vaccine) of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative and SARS-CoV-2 not detected by NAAT [nasal swab]) and had a negative NAAT (nasal swab) at any unscheduled visit up to 1 month after the booster dose were included in the analysis.

± All eligible participants who had received 2 doses of Pfizer-BioNTech COVID-19 Vaccine as initially randomized, with Dose 2 received within the predefined window (within 19 to 42 days after Dose 1), received a booster dose of Pfizer-BioNTech COVID-19 Vaccine, had at least 1 valid and determinate immunogenicity result after booster dose from a blood collection within an appropriate window (within 28 to 42 days after the booster dose), and had no other important protocol deviations as determined by the clinician.

a. n = Number of participants with valid and determinate assay results at both sampling time points within specified window.

b. GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.

c. GMRs and 2-sided 97.5% CIs were calculated by exponentiating the mean differences in the logarithms of the assay and the corresponding CIs (based on the Student t distribution).

d. Noninferiority is declared if the lower bound of the 2-sided 97.5% CI for the GMR is >0.67 and the point estimate of the GMR is ≥0.80.

e. SARS-CoV-2 NT50 were determined using the SARS-CoV-2 mNeonGreen Virus Microneutralization Assay. The assay uses a fluorescent reporter virus derived from the USA_WA1/2020 strain and virus neutralization is read on Vero cell monolayers. The sample NT50 is defined as the reciprocal serum dilution at which 50% of the virus is neutralized.

Table 14: Seroresponse Rate for 50% Neutralizing Titer (SARS-CoV-2 USA_WA1/2020) – Comparison of 1 Month After Booster Dose to 1 Month After Primary Series – Participants 18 Through 55 Years of Age Without Evidence of Infection up to 1 Month After Booster Dose* – Booster Dose Evaluable Immunogenicity Population±

Assay	N[a]	1 Month After Booster Dose n[b] % (95% CI[c])	1 Month After Primary Series n[b] % (95% CI[c])	Difference (1 Month After Booster Dose - 1 Month After Primary Series) %[d] (97.5% CI[e])	Met Noninferiority Objective[f] (Y/N)
SARS-CoV-2 neutralization assay - NT50 (titer)[g]	200	199 99.5 (97.2, 100.0)	196 98.0 (95.0, 99.5)	1.5 (-0.7, 3.7)	Y

Abbreviations: CI = confidence interval; LLOQ = lower limit of quantitation; N-binding = SARS-CoV-2 nucleoprotein-binding; NAAT = nucleic acid amplification test; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; Y/N = yes/no.

Note: Seroresponse is defined as achieving a ≥4-fold rise from baseline (before Dose 1). If the baseline measurement is below the LLOQ, a postvaccination assay result ≥4 × LLOQ is considered a seroresponse.

* Participants who had no serological or virological evidence (up to 1 month after receipt of booster vaccination) of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative and SARS-CoV-2 not detected by NAAT [nasal swab]) and had a negative NAAT (nasal swab) at any unscheduled visit up to 1 month after booster vaccination were included in the analysis.

± All eligible participants who had received 2 doses of Pfizer-BioNTech COVID-19 Vaccine as initially randomized, with Dose 2 received within the predefined window (within 19 to 42 days after Dose 1), received a booster dose of Pfizer-BioNTech COVID-19 Vaccine, had at least 1 valid and determinate immunogenicity result after booster dose from a blood collection within an appropriate window (within 28 to 42 days after the booster dose), and had no other important protocol deviations as determined by the clinician.

a. N = number of participants with valid and determinate assay results for the specified assay at baseline, 1 month after Dose 2 and 1 month after the booster dose within specified window. These values are the denominators for the percentage calculations.

b. n = Number of participants with seroresponse for the given assay at the given dose/sampling time point.

c. Exact 2-sided CI based on the Clopper and Pearson method.

d. Difference in proportions, expressed as a percentage (1 month after booster dose – 1 month after Dose 2).

e. Adjusted Wald 2-sided CI for the difference in proportions, expressed as a percentage.

f. Noninferiority is declared if the lower bound of the 2-sided 97.5% CI for the percentage difference is > -10%.

g. SARS-CoV-2 NT50 were determined using the SARS-CoV-2 mNeonGreen Virus Microneutralization Assay. The assay uses a fluorescent reporter virus derived from the USA_WA1/2020 strain and virus neutralization is read on Vero cell monolayers. The sample NT50 is defined as the reciprocal serum dilution at which 50% of the virus is neutralized.

18.5 Immunogenicity in Solid Organ Transplant Recipients

From an independent report *(Kamar N, Abravanel F, Marion O, et al. Three doses of an mRNA Covid-19 vaccine in solid-organ transplant recipients. N Engl J Med)*, a single arm study has been conducted in 101 individuals who had undergone various solid organ transplant procedures (heart, kidney, liver, lung, pancreas) 97±8 months previously. A third dose of the Pfizer-BioNTech COVID-19 vaccine was administered to 99 of these individuals approximately 2 months after they had received a second dose. Among the 59 patients who had been seronegative before the third dose, 26 (44%) were seropositive at 4 weeks after the third dose. All 40 patients who had been seropositive before the third dose were still seropositive 4 weeks later. The prevalence of anti-SARS-CoV-2 antibodies was 68% (67 of 99 patients) 4 weeks after the third dose.

19 HOW SUPPLIED/STORAGE AND HANDLING

Pfizer-BioNTech COVID-19 Vaccine Suspension for Intramuscular Injection, Multiple Dose Vials are supplied in a carton containing 25 multiple dose vials (NDC 59267-1000-3) or 195 multiple dose vials (NDC 59267-1000-2). After dilution, one vial contains 6 doses of 0.3 mL. Vial labels and cartons may state that after dilution, a vial contains 5 doses of 0.3 mL. The information in this Full EUA Prescribing Information

regarding the number of doses per vial after dilution supersedes the number of doses stated on vial labels and cartons.

During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

Do not refreeze thawed vials.

Frozen Vials Prior to Use

Cartons of Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vials arrive in thermal containers with dry ice. Once received, remove the vial cartons immediately from the thermal container and preferably store in an ultra-low temperature freezer between -90°C to -60°C (-130°F to -76°F) until the expiry date printed on the label. This information in the package insert supersedes the storage conditions printed on the vial cartons.

Cartons and vials of Pfizer-BioNTech COVID-19 Vaccine with an expiry date of May 2021 through February 2022 printed on the label may remain in use for 3 months beyond the printed date as long as approved storage conditions between -90°C to -60°C (-130°F to -76°F) have been maintained. Updated expiry dates are shown below.

Printed Expiry Date		Updated Expiry Date
May 2021	→	August 2021
June 2021	→	September 2021
July 2021	→	October 2021
August 2021	→	November 2021
September 2021	→	December 2021
October 2021	→	January 2022
November 2021	→	February 2022
December 2021	→	March 2022
January 2022	→	April 2022
February 2022	→	May 2022

If not stored between -90°C to -60°C (-130°F to -76°F), vials may be stored at -25°C to -15°C (-13°F to 5°F) for up to 2 weeks. Vials must be kept frozen and protected from light, in the original cartons, until ready to use. Vials stored at -25°C to -15°C (-13°F to 5°F) for up to 2 weeks may be returned one time to the recommended storage condition of -90°C to -60°C (-130°F to -76°F). Total cumulative time the vials are stored at -25°C to -15°C (-13°F to 5°F) should be tracked and should not exceed 2 weeks.

If an ultra-low temperature freezer is not available, the thermal container in which the Pfizer-BioNTech COVID-19 Vaccine arrives may be used as temporary storage when consistently re-filled to the top of the container with dry ice. Refer to the re-icing guidelines packed in the original thermal container for instructions regarding the use of the thermal container for temporary storage. The thermal container maintains a temperature range of -90°C to -60°C (-130°F to -76°F). Storage of the vials between -96°C to -60°C (-141°F to -76°F) is not considered an excursion from the recommended storage condition.

Transportation of Frozen Vials

If local redistribution is needed and full cartons containing vials cannot be transported at -90°C to -60°C (-130°F to -76°F), vials may be transported at -25°C to -15°C (-13°F to 5°F). Any hours used for transport at -25°C to -15°C (-13°F to 5°F) count against the 2-week limit for storage at -25°C to -15°C (-13°F to 5°F). Frozen vials transported at -25°C to -15°C (-13°F to 5°F) may be returned one time to the recommended storage condition of -90°C to -60°C (-130°F to -76°F).

Thawed Vials Before Dilution

Thawed Under Refrigeration

Thaw and then store undiluted vials in the refrigerator [2°C to 8°C (35°F to 46°F)] for up to 1 month. A carton of 25 vials or 195 vials may take up to 2 or 3 hours, respectively, to thaw in the refrigerator, whereas a fewer number of vials will thaw in less time.

Thawed at Room Temperature

For immediate use, thaw undiluted vials at room temperature [up to 25°C (77°F)] for 30 minutes. Thawed vials can be handled in room light conditions.

Vials must reach room temperature before dilution.

Undiluted vials may be stored at room temperature for no more than 2 hours.

Transportation of Thawed Vials

Available data support transportation of one or more thawed vials at 2°C to 8°C (35°F to 46°F) for up to 12 hours.

Vials After Dilution

After dilution, store vials between 2°C to 25°C (35°F to 77°F) and use within 6 hours from the time of dilution. During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. Any vaccine remaining in vials must be discarded after 6 hours. Do not refreeze.

20 PATIENT COUNSELING INFORMATION

Advise the recipient or caregiver to read the Vaccine Information Fact Sheet for Recipients and Caregivers.

The vaccination provider must include vaccination information in the state/local jurisdiction's Immunization Information System (IIS) or other designated system. Advise recipient or caregiver that more information about IISs can be found at: https://www.cdc.gov/vaccines/programs/iis/about.html.

21 CONTACT INFORMATION

For general questions, visit the website or call the telephone number provided below.

Website	Telephone number
www.cvdvaccine.com	1-877-829-2619 (1-877-VAX-CO19)

This Full EUA Prescribing Information may have been updated. For the most recent Full EUA Prescribing Information, please see www.cvdvaccine.com.

Pfizer

Manufactured by
Pfizer Inc., New York, NY 10017

BIONTECH

Manufactured for
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An der Goldgrube 12
55131 Mainz, Germany

LAB-1457-13.4

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Vaccines and Related Biological Products Advisory Committee October 22, 2020 Meeting Presentation

Individuals using assistive technology may not be able to fully access the information contained in this file. For assistance, please send an e-mail to: ocod@fda.hhs.gov and include 508 Accommodation and the title of the document in the subject line of your e-mail.

U.S. FOOD & DRUG ADMINISTRATION

CBER Plans for Monitoring COVID-19 Vaccine Safety and Effectiveness

Steve Anderson, PhD, MPP
Director, Office of Biostatistics & Epidemiology, CBER

VRBPAC Meeting
October 22, 2020

FDA Vaccine Surveillance: Pre-licensure Pharmacovigilance Planning

"Safety throughout the lifecycle" approach for vaccines (pre- and post-licensure):

- Manufacturer submits pharmacovigilance plans (PVP) of proposed post-licensure surveillance activities

  Submitted for BLA and for EUA

  Post-licensure commitment (PMC) – studies, registries for general safety concern

  Post-licensure requirement (PMR) – clinical study, epidemiological study, registries, etc. to verify a specific safety signal

  Routine pharmacovigilance – Passive surveillance (VAERS), review of safety literature, available studies, etc.

FDA Vaccine Surveillance Programs: Post-Licensure

1. **Passive Surveillance of Vaccines**

   Vaccine Adverse Event Reporting System (VAERS)

   - Management shared by CDC and FDA

2. **Active Surveillance Monitoring Program**

   FDA BEST

   FDA-CMS partnership

FDA Vaccine Surveillance Programs: Post-Licensure

1. Passive Surveillance of Vaccines

   Vaccine Adverse Event Reporting System (VAERS)

   - Management shared by CDC and FDA

2.

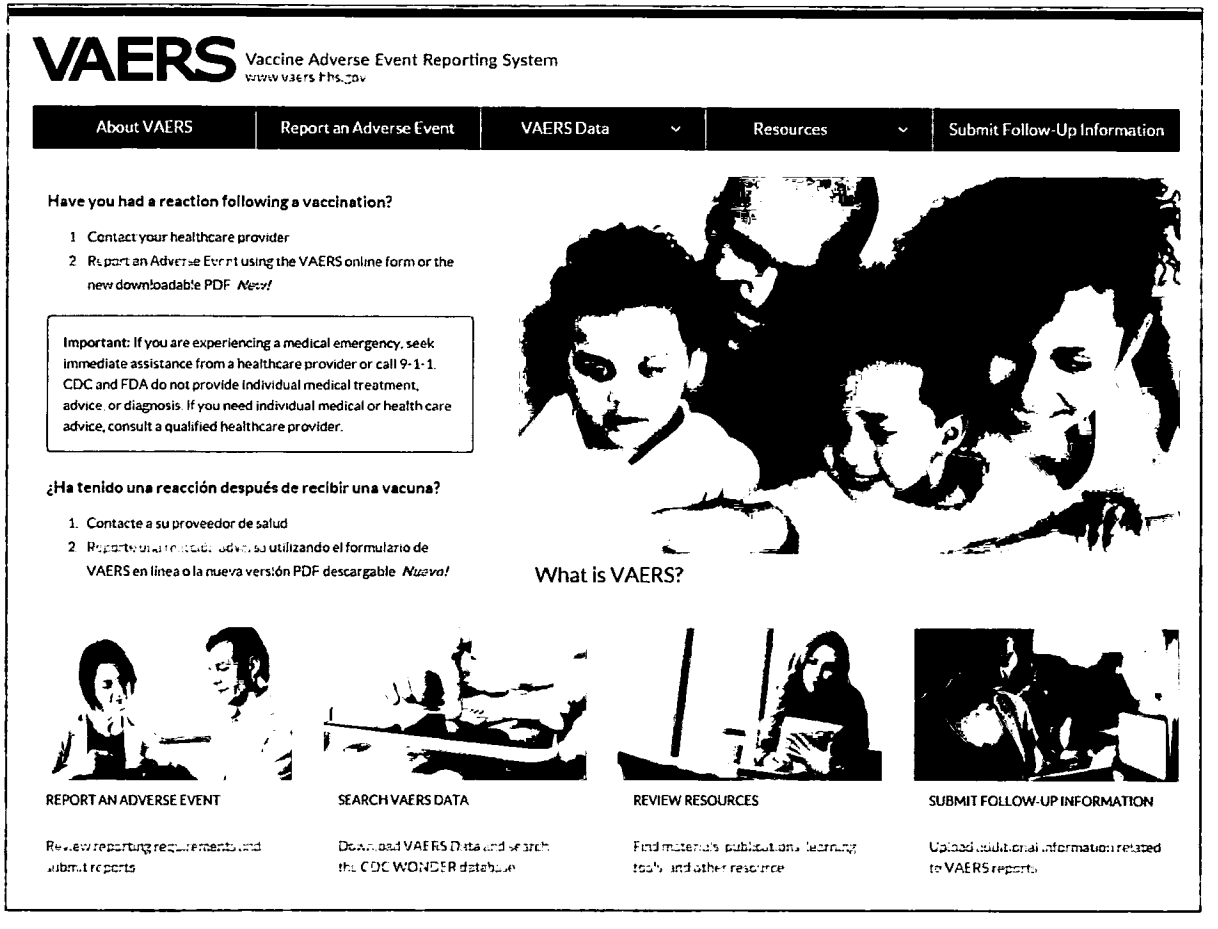
VAERS

Vaccine Adverse Event Reporting System

Co-managed by CDC and FDA

CDC + FDA

http://vaers.hhs.gov



VAERS – FDA CBER Efforts

- CDC presentation covered VAERS so will provide summary of FDA efforts
- **FDA and CDC have weekly and bi-weekly coordination meetings** on VAERS and Pharmacovigilance activities between CBER OBE and OBE Division of Epidemiology (DE) and CDC Immunization Safety Office
- **CBER DE Physicians will be reviewing the serious adverse event reports** from VAERS for COVID-19 vaccines – review of individual reports, death reports, conduct aggregate analyses, case-series, etc.
- **FDA will utilize statistical data-mining methods** to detect disproportional reporting of specific vaccine-adverse event combinations to identify AEs that are more frequently reported

FDA Vaccine Surveillance Programs: Post-Licensure

1.

2. Active Surveillance Monitoring Program

   FDA BEST

   FDA-CMS partnership

FDA Vaccine– Legislative Authorization Active Surveillance

Legislation, mandates and Current Surveillance

FDA Amendments Act of 2007:

- Directed FDA to develop an active risk identification and analysis system – such as Sentinel, and later BEST, and others and covers ≥100 million persons

Prescription Drug User Fee Act VI (2017)

- Discussion between FDA and Industry on Priority Areas - Renewed every 5 yrs
- Provides resources/funding for Sentinel, BEST, real-world evidence, etc

COVID-19 Vaccine Monitoring Data Considerations

- **Rapid data access** for near real time surveillance
- **Large databases of tens of millions of patients** for evaluating vaccine rare serious adverse events
- **Data representing integrated care spectrum** – outpatient, physician, inpatient, etc.
- **High quality data** to assess and confirm potential adverse events or safety concerns for COVID-19 vaccines
- **Data with significant clinical detail** or medical chart access

1. FDA Biologics Effectiveness and Safety (BEST) System

Several partners – Acumen, IBM Watson, IQVIA, OHDSI, HealthCore, Humana, Optum, Healthagen, Academic organizations

Represents variety of healthcare settings – inpatient, emergency department, outpatient, etc.

BEST Initiative Expansion

CLAIMS Data Sources

Data Sources	Type	Patients (millions)
MarketScan	Claims	254
Blue Health Intelligence	Claims	33.6
Optum	Claims	70
HealthCore	Claims	56
Healthagen	Claims	26
OneFlorida Clinical Research Consortium (Medicaid)	Claims	6.7

Data lag: 1-12 months depending on data source

BEST Initiative Expansion
EHR Data Sources

Data Sources	Type	Patients (millions)
MedStar Health	EHR	6
IBM Explorys	EHR	90
Regenstrief Institute	Claims and EHR	20.2
Columbia University	EHR	6.6
University of Colorado	EHR	17
University of California San Francisco	EHR	3.2
PEDSnet Clinical Research Consortium	EHR	6.2
Optum EHR	EHR	105
OneFlorida Clinical Research Consortium	EHR	5.6
OneFlorida Clinical Research Consortium	Linked EHR-Claims	1.5
MarketScan Explorys Claims-EHR (CED)	Linked EHR-Claims	5.5
Optum	Linked EHR-Claims	50

Data lag: 1-2 weeks to 4 months depending on data source

2. CMS (Center for Medicare & Medicaid Services)

- **Federal Partners**
  - Ongoing FDA-CMS partnership on vaccine safety since 2002
  - Data cover very large population of approximately 55 million elderly US beneficiaries ≥65yrs of age
  - >92% of US elderly use Medicare so database represents the elderly population and not a sample
  - Represents variety of healthcare settings – inpatient, outpatient, etc.
  - Consists of claims data with access to medical charts

Limitations of Data Systems

- Not all claims and EHR data systems can be used to address a vaccine safety or effectiveness regulatory question

- Each data system has its limitations
  - Populations, healthcare settings, clinical detail, necessary parameters, data lag, exposures and outcomes that are captured

FDA COVID-19 vaccine safety surveillance planning

"Near real-time surveillance" or rapid-cycle analyses (RCA)

- FDA plans on monitoring 10 -20 safety outcomes of interest to be determined based on:
  - Pre-market review of sponsor safety data submitted to FDA
  - In coordination with federal partners, international regulatory partners and organizations, academic experts, others
  - Literature and regulatory experience with similar vaccines, novel vaccine platforms, and using other relevant data
  - FDA plans on using CMS data for COVID-19 vaccine RCA – near real time with efforts

FDA Safety Surveillance of COVID-19 Vaccines :
DRAFT Working list of possible adverse event outcomes
Subject to change

- Guillain-Barré syndrome
- Acute disseminated encephalomyelitis
- Transverse myelitis
- Encephalitis/myelitis/encephalomyelitis/ meningoencephalitis/meningitis/ encepholapathy
- Convulsions/seizures
- Stroke
- Narcolepsy and cataplexy
- Anaphylaxis
- Acute myocardial infarction
- Myocarditis/pericarditis
- Autoimmune disease
- Deaths
- Pregnancy and birth outcomes
- Other acute demyelinating diseases
- Non-anaphylactic allergic reactions
- Thrombocytopenia
- Disseminated intravascular coagulation
- Venous thromboembolism
- Arthritis and arthralgia/joint pain
- Kawasaki disease
- Multisystem Inflammatory Syndrome in Children
- Vaccine enhanced disease

FDA Experience with Near Real Time Surveillance / RCA

FDA and CMS - RCA

- Conduct "near real-time" surveillance for annual influenza vaccine and Guillain-Barre Syndrome(GBS) since 2007
- Support confirmation of CDC rapid-cycle analyses of safety for seasonal influenza vaccine, Shingrix, and others

FDA Sentinel – Rapid Surveillance

- Near real-time, rapid surveillance in 2017-2018 seasonal influenza vaccine – evaluation of 6 health outcomes of interest

FDA COVID-19 vaccine safety surveillance Plans

- **Epidemiological analyses**
  - Need capability to resolve potential safety signals identified from near real-time surveillance, TreeScan and other sources
  - Rapid queries and small epidemiological studies
  - Larger self-controlled, cohort, comprehensive protocol-based studies

COVID-19 Vaccine Effectiveness Surveillance Plans

- COVID-19 vaccine(s) – there may be limited information available at licensure on level and duration of effectiveness
- Manufacturers may conduct certain COVID-19 vaccine effectiveness post-licensure studies
- FDA may conduct COVID-19 vaccine effectiveness studies
  - General effectiveness studies – including subpopulations of interest
  - Duration of protection studies
  - Others
- FDA coordinating COVID-19 Vaccine Effectiveness efforts with the CDC NCIRD through monthly, bi-monthly meetings

FDA-CMS-CDC Vaccine Effectiveness Experience

- Extensive experience with the data and methods needed to conduct vaccine effectiveness studies
- Produced several vaccine effectiveness and relative vaccine effectiveness studies for influenza and zoster vaccines
- Conducted duration of effectiveness analysis of Zostavax vaccine

FDA-CMS Vaccine Effectiveness Experience

- Actively studying risk factors for COVID-19 and preparing to study safety and effectiveness of vaccines and biologics therapies
- More than 30 publications since 2012
- Results included in Congressional testimony

CBER COVID-19 Vaccine Monitoring Transparency Considerations

- Master Protocols for Safety and Effectiveness outcomes
- Posting of draft protocols for public comment
- Posting of final protocols and final study reports on the BESTinitiative.org website

US Government-wide Efforts COVID-19 Vaccine Monitoring

Large US Government Effort

FDA Coordinating its COVID-19 vaccine safety and effectiveness monitoring efforts with other government agencies:

- Centers for Disease Control (CDC)
- Centers for Medicare& Medicaid Services (CMS)
- Veterans Administration (VA)
- National Institutes of Health
- Department of Defense
- Indian Health Services

US Government-wide Efforts
COVID-19 Vaccine Monitoring (2)

Large US Government Effort

- Weekly meetings between FDA and CDC, regular meetings with VA and CMS
- Planned sharing of protocols, discussion safety and effectiveness outcomes of interest
- Coordinated planning and conduct of surveillance activities such as near real time surveillance/ RCA between FDA, CDC, CMS, VA, and DOD

Acknowledgments

- Richard Forshee
- Azadeh Shoaibi
- Hui-Lee Wong
- CBER Surveillance Team
- Manette Niu
- CBER OBE Colleagues
- CDC Colleagues
- CMS Colleagues
- VA Colleagues
- FDA Partners: Acumen, IBM Watson – and new partners in FY2021

U.S. FOOD & DRUG ADMINISTRATION

Thank you!

Questions?

Centers for Disease Control and Prevention

COVID-19

Selected Adverse Events Reported after COVID-19 Vaccination

Updated Oct. 6, 2021

Safety of COVID-19 Vaccines

Some people have no side effects. Many people have reported side effects that may affect their ability to do daily activities, but they should go away within a few days.

What You Need to Know

- COVID-19 vaccines are safe and effective.
- Millions of people in the United States have received COVID-19 vaccines under the most intense safety monitoring in U.S. history.
- CDC recommends everyone 12 years and older get vaccinated as soon as possible to help protect against COVID-19 and the related, potentially severe complications that can occur.
- CDC, the U.S. Food and Drug Administration (FDA), and other federal agencies are monitoring the safety of COVID-19 vaccines.
- Adverse events described on this page have been reported to the Vaccine Adverse Event Reporting System (VAERS) .
- VAERS accepts reports of any adverse event following any vaccination.
- Reports of adverse events to VAERS following vaccination, including deaths, do not necessarily mean that a vaccine caused a health problem.

Serious adverse events after COVID-19 vaccination are rare but may occur.

For public awareness and in the interest of transparency, CDC is providing timely updates on the following serious adverse events of interest:

- Anaphylaxis after COVID-19 vaccination is rare and has occurred in approximately 2 to 5 people per million vaccinated in the United States. Severe allergic reactions, including anaphylaxis, can occur after any vaccination. If this occurs, vaccination providers can effectively and immediately treat the reaction. Learn more about COVID-19 vaccines and allergic reactions, including anaphylaxis.
- Thrombosis with thrombocytopenia syndrome (TTS) after Johnson & Johnson's Janssen (J&J/Janssen) COVID-19

EXHIBIT C-7

vaccination is rare. As of September 29, 2021, more than 14.9 million doses of the J&J/Janssen COVID-19 Vaccine have been given in the United States. CDC and FDA identified 47 confirmed reports of people who got the J&J/Janssen COVID-19 Vaccine and later developed TTS. Women younger than 50 years old especially should be aware of the rare but increased risk of this adverse event. There are other COVID-19 vaccine options available for which this risk has not been seen. Learn more about J&J/Janssen COVID-19 Vaccine and TTS.

> To date, two confirmed cases of TTS following mRNA COVID-19 vaccination (Moderna) have been reported to VAERS after more than 376 million doses of mRNA COVID-19 vaccines administered in the United States. Based on available data, there is not an increased risk for TTS after mRNA COVID-19 vaccination.

CDC and FDA are monitoring reports of Guillain-Barré Syndrome (GBS) in people who have received the J&J/Janssen COVID-19 Vaccine. GBS is a rare disorder where the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis. Most people fully recover from GBS, but some have permanent nerve damage. After more than 14.9 million J&J/Janssen COVID-19 Vaccine doses administered, there have been around 219 preliminary reports of GBS identified in VAERS as of September 29, 2021. These cases have largely been reported about 2 weeks after vaccination and mostly in men, many 50 years and older. CDC will continue to monitor for and evaluate reports of GBS occurring after COVID-19 vaccination and will share more information as it becomes available.

Myocarditis and pericarditis after COVID-19 vaccination are rare. As of September 29, 2021, VAERS has received 1,590 reports of myocarditis or pericarditis among people ages 30 and younger who received COVID-19 vaccine. Most cases have been reported after mRNA COVID-19 vaccination (Pfizer-BioNTech or Moderna), particularly in male adolescents and young adults. Through follow-up, including medical record reviews, CDC and FDA have confirmed 906 reports of myocarditis or pericarditis. CDC and its partners are investigating these reports to assess whether there is a relationship to COVID-19 vaccination. Learn more about COVID-19 vaccines and myocarditis.

Reports of death after COVID-19 vaccination are rare. More than 396 million doses of COVID-19 vaccines were administered in the United States from December 14, 2020, through October 4, 2021. During this time, VAERS received 8,390 reports of death (0.0021%) among people who received a COVID-19 vaccine. FDA requires healthcare providers to report any death after COVID-19 vaccination to VAERS, even if it's unclear whether the vaccine was the cause. Reports of adverse events to VAERS following vaccination, including deaths, do not necessarily mean that a vaccine caused a health problem. A review of available clinical information, including death certificates, autopsy, and medical records, has not established a causal link to COVID-19 vaccines. However, recent reports indicate a plausible causal relationship between the J&J/Janssen COVID-19 Vaccine and TTS, a rare and serious adverse event—blood clots with low platelets—which has caused deaths [1.4 MB, 40 pages].

Related Pages

- Safety of COVID-19 Vaccines
- Vaccine Adverse Event Reporting System (VAERS): What Reports Mean and How VAERS Works

Last Updated Oct. 6, 2021

Read The CDC Disclaimer

VAERS COVID Vaccine Adverse Event Reports

Reports from the Vaccine Adverse Events Reporting System. Our default data reflects all VAERS data including the "nondomestic" reports.

All VAERS COVID Reports | US/Territories/Unknown

593,727 (US) Reports Through October 01, 2021

7,437	34,880	74,520
DEATHS	HOSPITALIZATIONS	URGENT CARE

111,694	1,977	2,574
DOCTOR OFFICE VISITS	ANAPHYLAXIS	BELL'S PALSY

EXHIBIT C-8

1,226
Miscarriages

3,841
Heart Attacks

3,123
Myocarditis/Pericarditis

8,088
Permanently Disabled

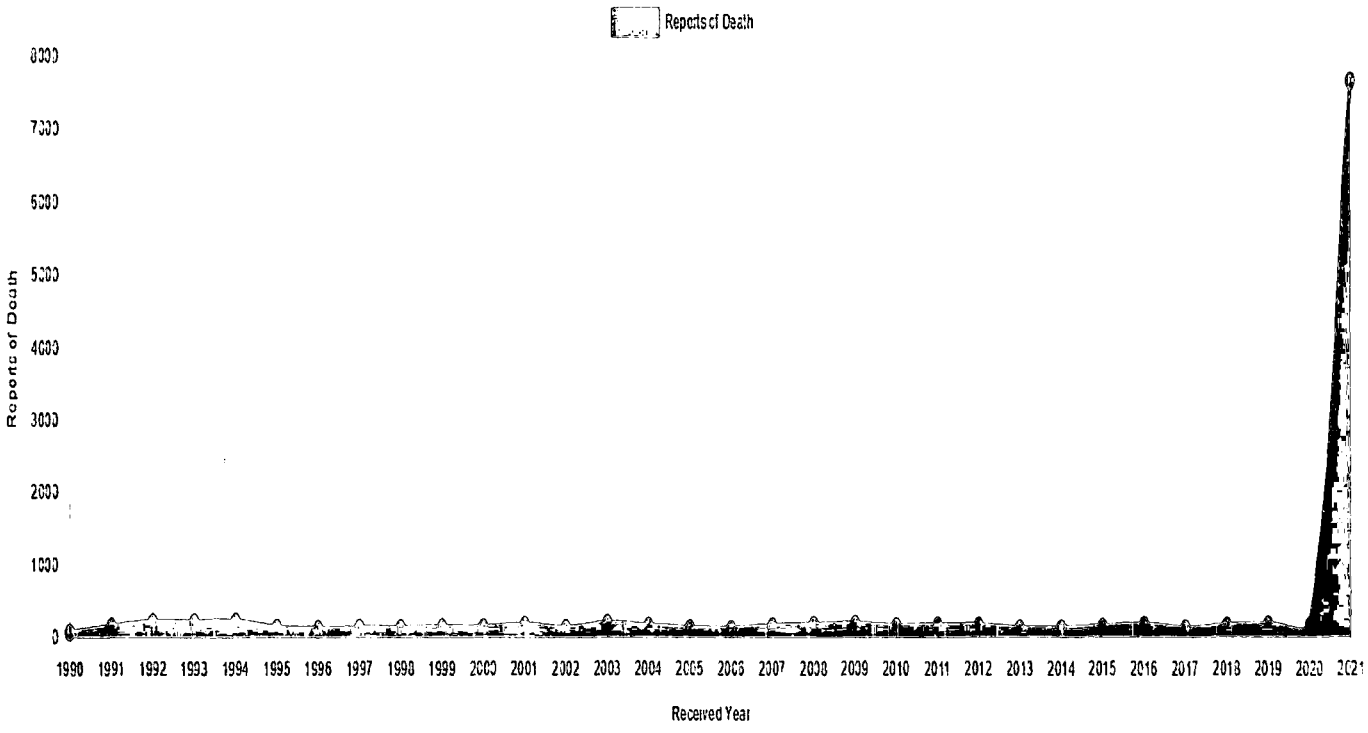
1,165
Thrombocytopenia/
Low Platelet

9,012
Life Threatening

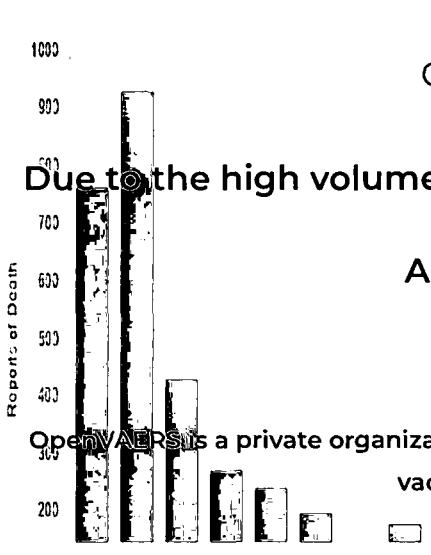
23,730
Severe Allergic Reaction

6,202
Shingles

All US Deaths Reported to VAERS by Year



VAERS COVID Vaccine Reports of Deaths by Days to Onset All Ages - US Only



Questions? Comments? Bugs?

info@openvaers.com

Due to the high volume of inquiries, please be patient with response times.

AND PLEASE read the FAQ first.

OpenVAERS is a private organization that posts publicly available CDC/FDA data of injuries reported post-vaccination. Reports are not proof of causality.

Read The CDC Disclaimer

VAERS COVID Vaccine Adverse Event Reports

Reports from the Vaccine Adverse Events Reporting System. Our default data reflects all VAERS data including the "nondomestic" reports.

All VAERS COVID Reports | US/Territories/Unknown

778,683 Reports Through October 01, 2021

16,310	75,605	87,814
DEATHS	HOSPITALIZATIONS	URGENT CARE

121,305	7,141	9,446
DOCTOR OFFICE VISITS	ANAPHYLAXIS	BELL'S PALSY

EXHIBIT C-9

2,415
Miscarriages

7,868
Heart Attacks

8,689
Myocarditis/Pericarditis

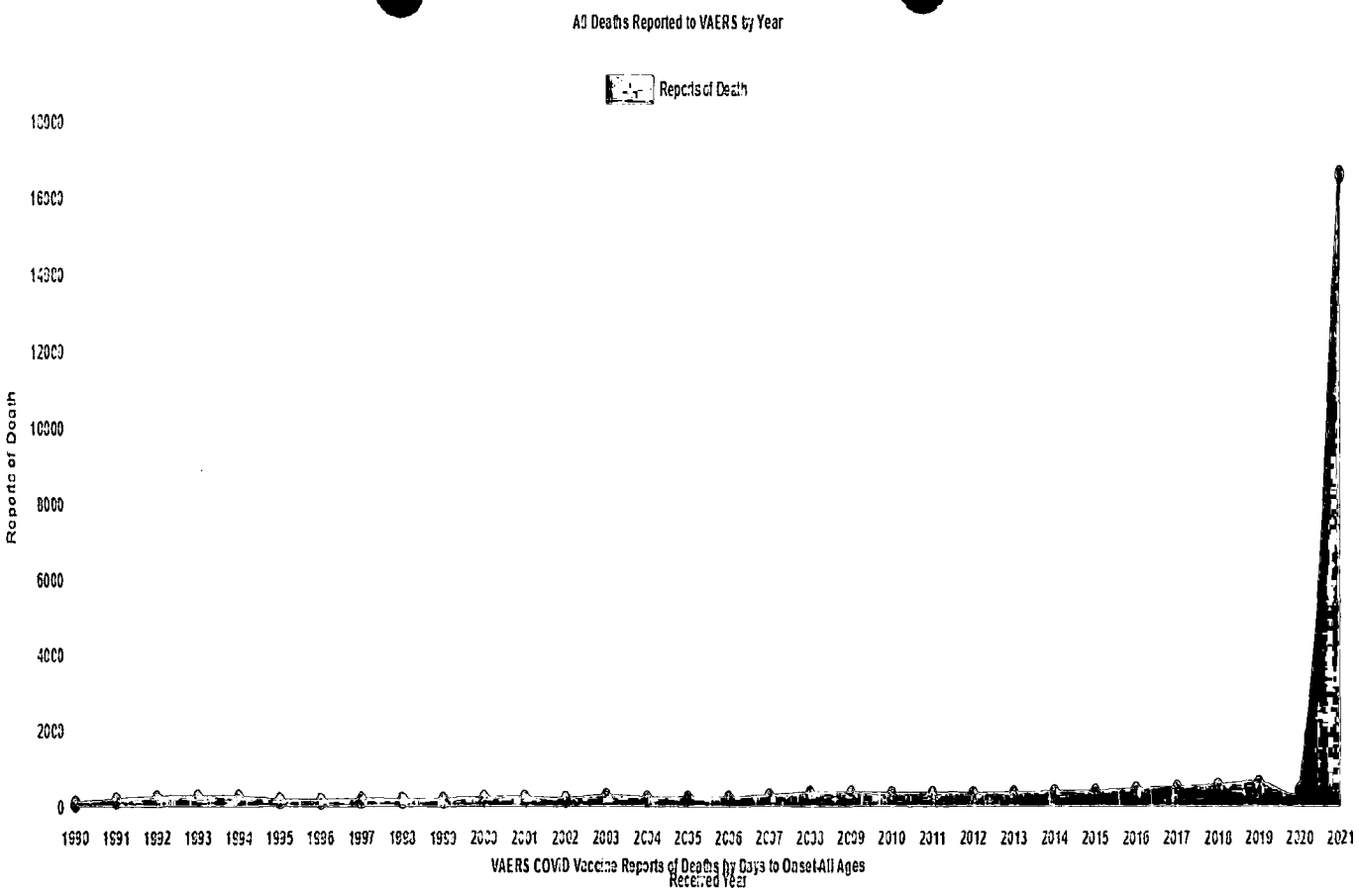
23,712
Permanently Disabled

3,620
Thrombocytopenia/
Low Platelet

17,619
Life Threatening

30,631
Severe Allergic Reaction

9,215
Shingles



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VAERS COVID Vaccine Mortality Reports

Through October 01, 2021

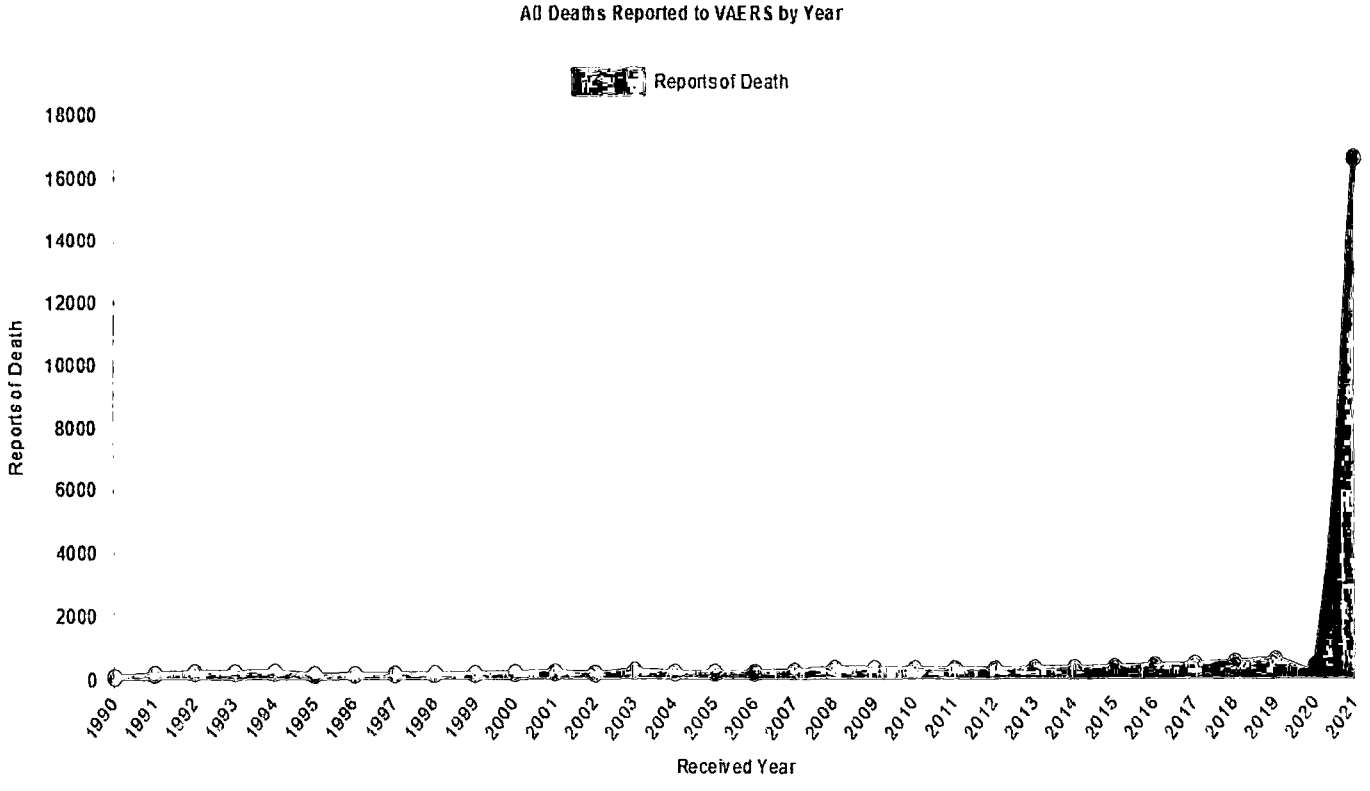
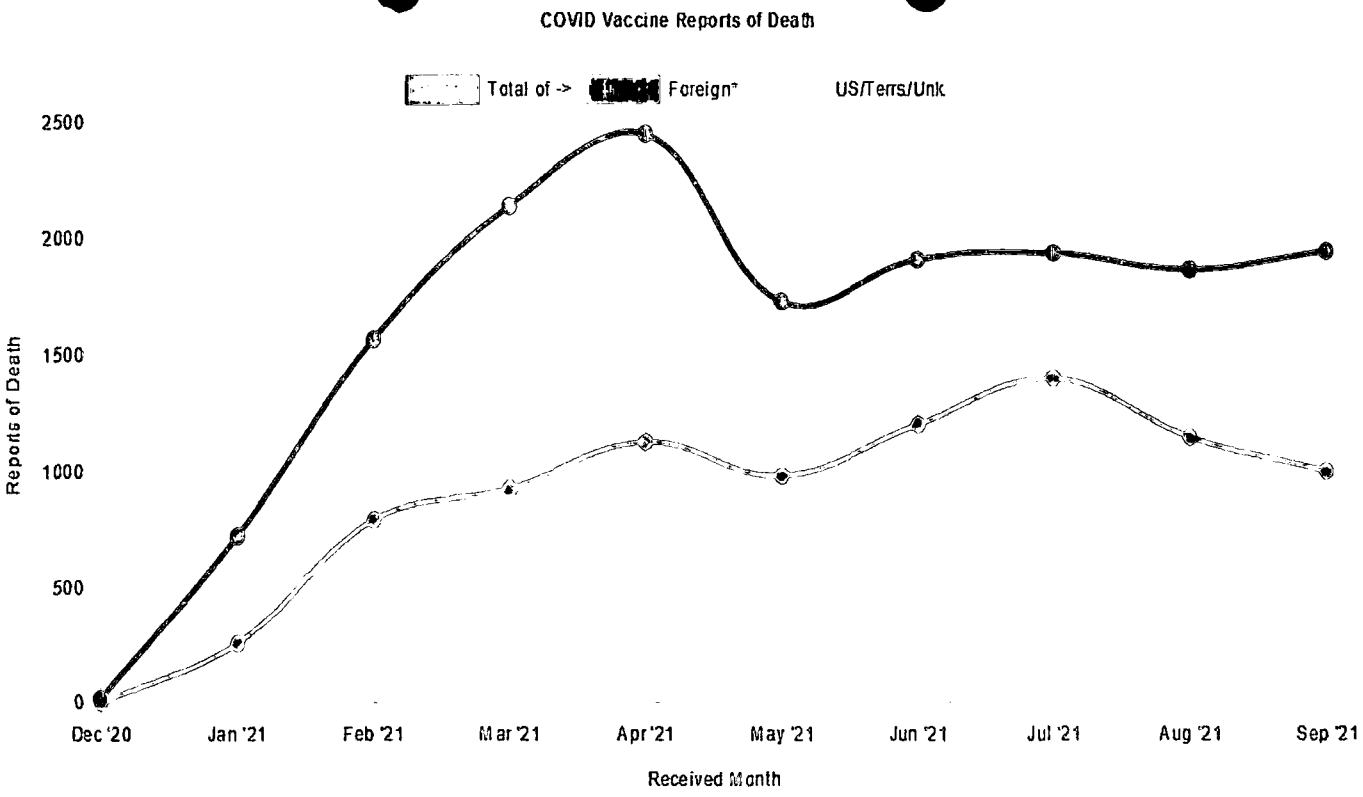
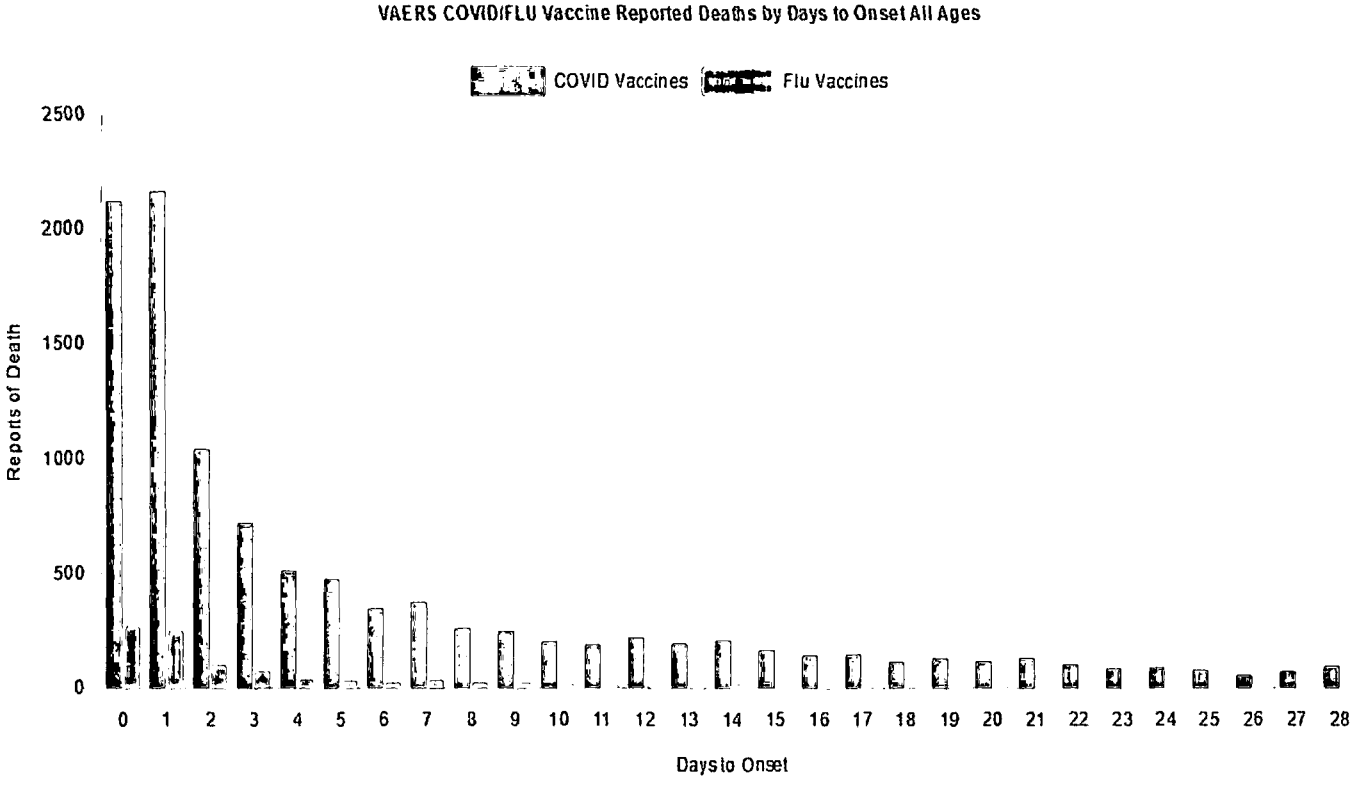


EXHIBIT C-10





Read what VAERS says about Foreign Reports

MANUFACTURER	DIED
Janssen	1172
Moderna	4017
Pfizer	11074
Unknown	47

SEX	DIED
F	7095
M	8370
U	845

AGE	DIED
Unk	6126
0-24	113
25-50	828
51-65	1682
66-80	3566
81+	3995

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VAERS COVID Vaccine Hospitalization Reports

Through October 01, 2021

MANUFACTURER	HOSPITALIZED
Janssen	5438
Moderna	18675
Pfizer	51304
Unknown	188

SEX	HOSPITALIZED
F	1912
M	2210
U	57

AGE	HOSPITALIZED
0-24	4167
Unk	24700
25-50	14215
51-65	11688
66-80	13371
81+	7464

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VAERS COVID Vaccine Urgent Care Visit Reports

Through October 01, 2021

MANUFACTURER	VISITS
Janssen	7790
Moderna	28439
Pfizer	51359
Unknown	226

SEX	VISITS
F	58844
M	28205
U	765

AGE	VISITS
0-24	8500
Unk	8321
25-50	35107
51-65	18872
66-80	12576
81+	4438

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VAERS COVID Vaccine Office Visit Reports

Through October 01, 2021

MANUFACTURER	VISITS
Janssen	10352
Moderna	47553
Pfizer	63168
Unknown	232

SEX	VISITS
F	86297
M	34222
U	786

AGE	VISITS
0-24	8706
Unk	6315
25-50	52785
51-65	30684
66-80	18959
81+	3856

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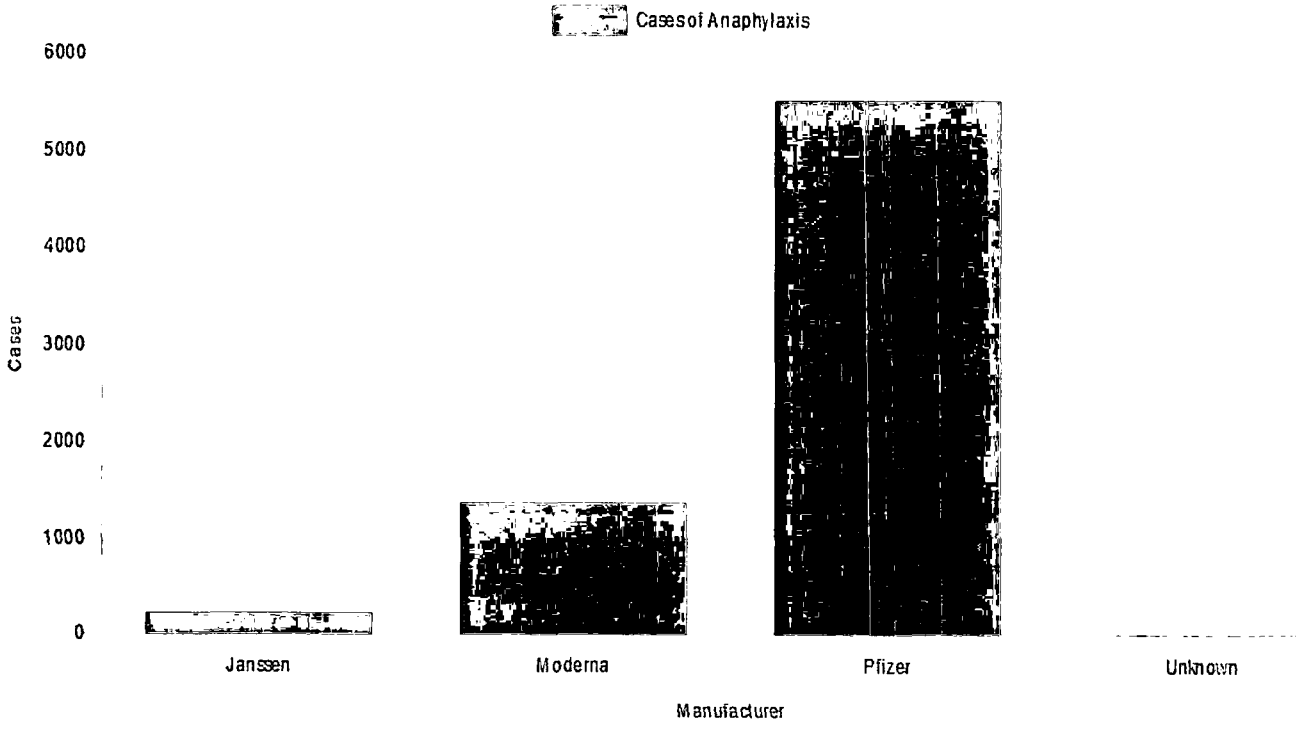
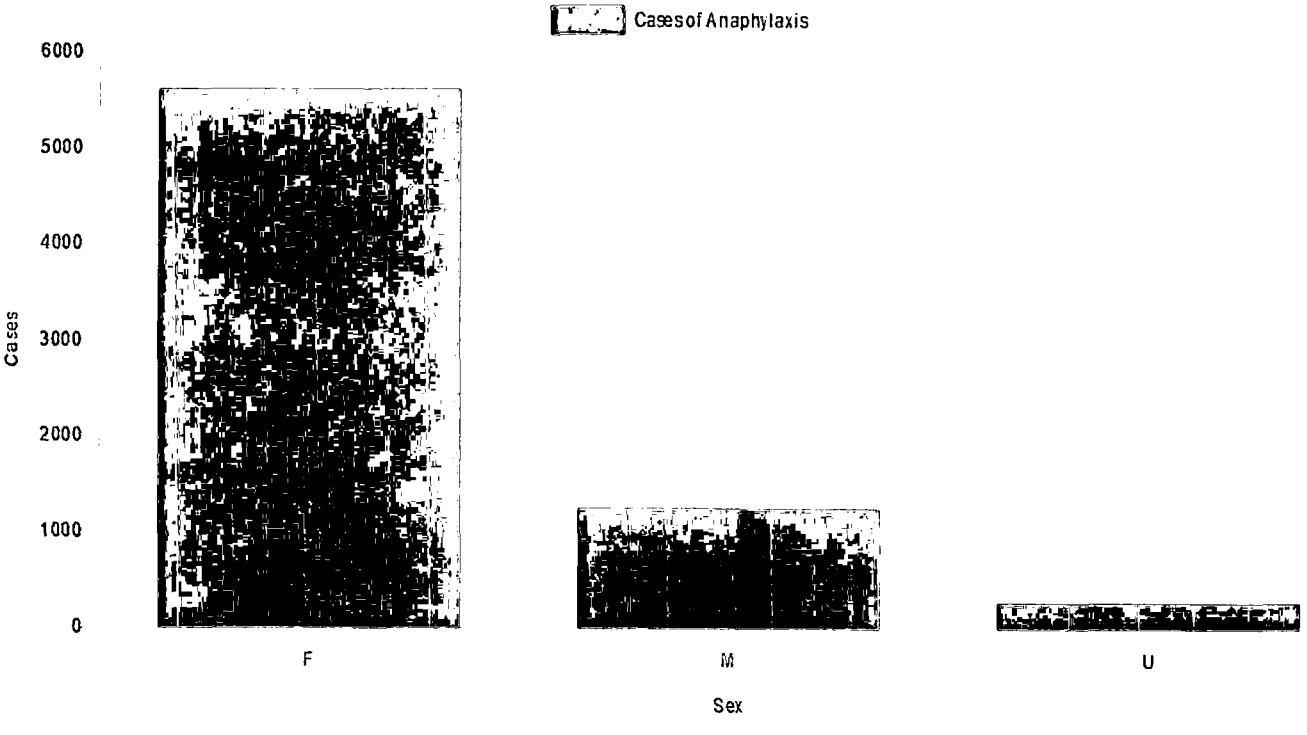
VAERS COVID Vaccine Anaphylaxis Reports

Through October 01, 2021

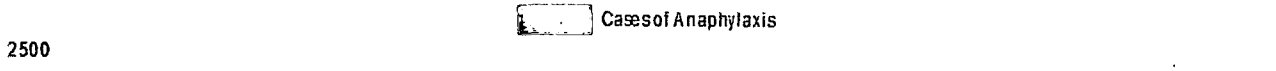
Anaphylaxis Cases Post Covid Vaccine by Manufacturer

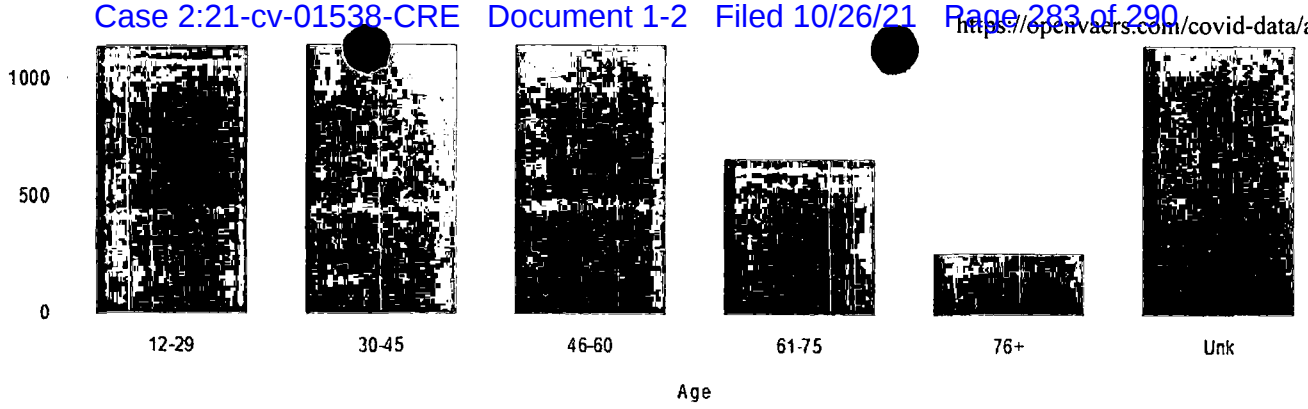


Anaphylaxis Cases Post Covid Vaccine by Sex



Anaphylaxis Cases Post Covid Vaccine by Age





MANUFACTURER	CASES
Janssen	229
Moderna	1378
Pfizer	5526
Unknown	8

SEX	CASES
F	5617
M	1249
U	275

AGE	CASES
12-29	1143
30-45	2113
46-60	1689
61-75	666
76+	263
Unk	1267

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Read The CDC Disclaimer

VAERS COVID Vaccine Bell's Palsy Reports

Through October 01, 2021

MANUFACTURER	CASES
Janssen	516
Moderna	2314
Pfizer	6595
Unknown	21

SEX	CASES
F	5351
M	3800
U	295

AGE	CASES
Unk	3242
0-24	314
25-50	2686
51-65	1781
66-80	1098
81+	325

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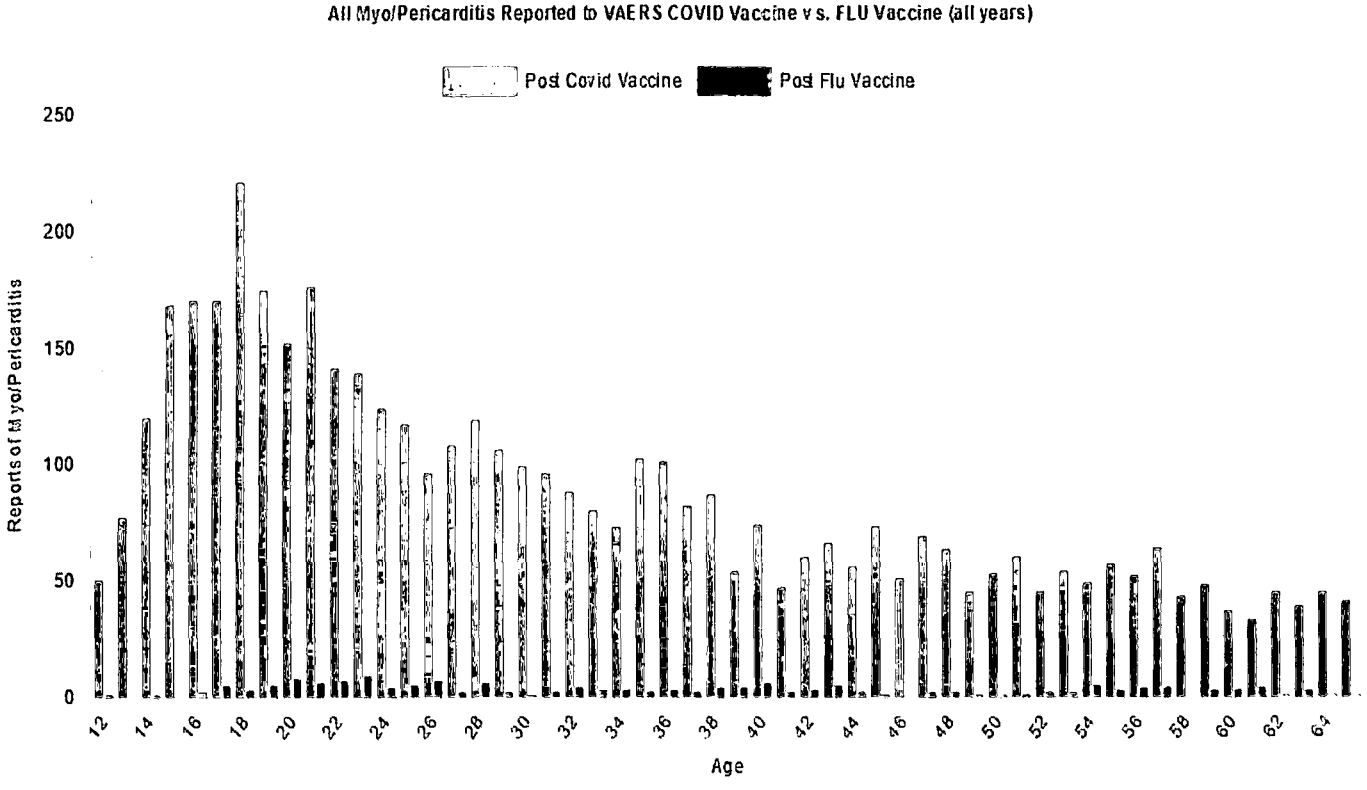
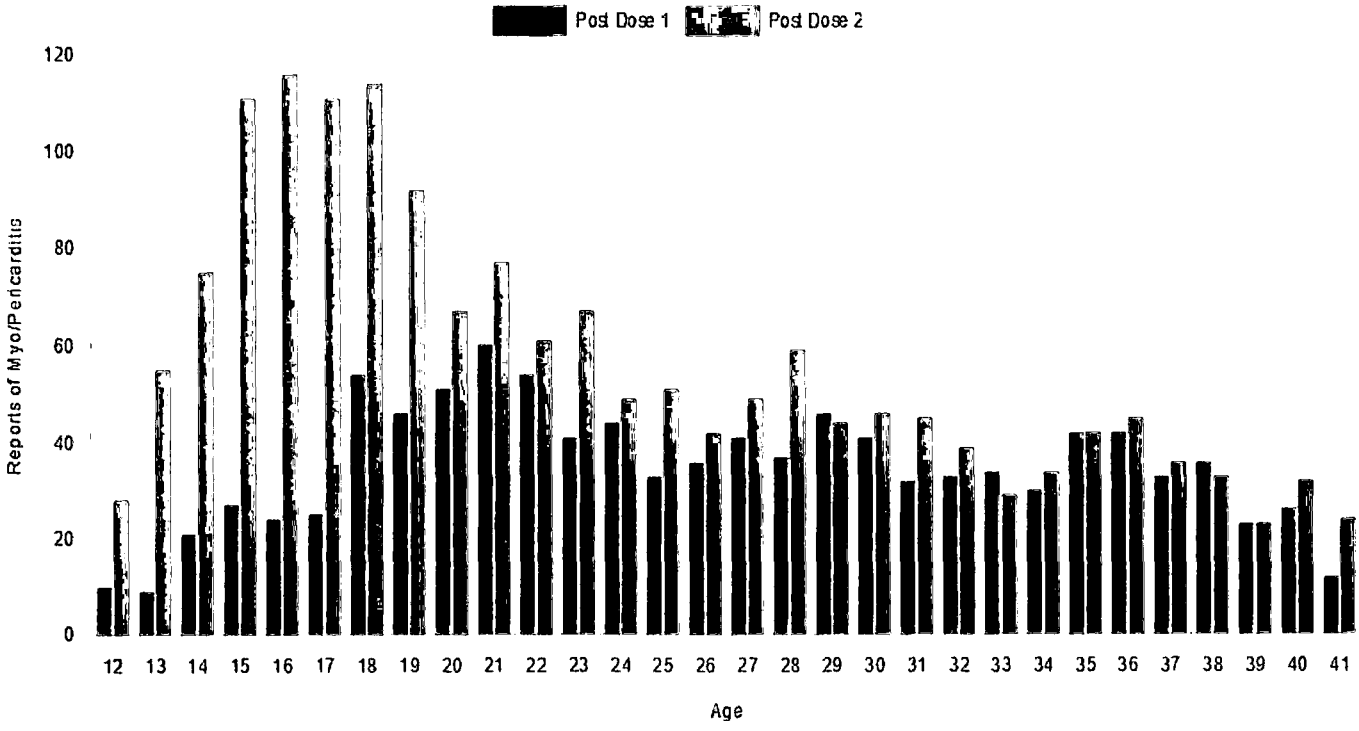
VAERS COVID Vaccine Myo/Pericarditis Reports

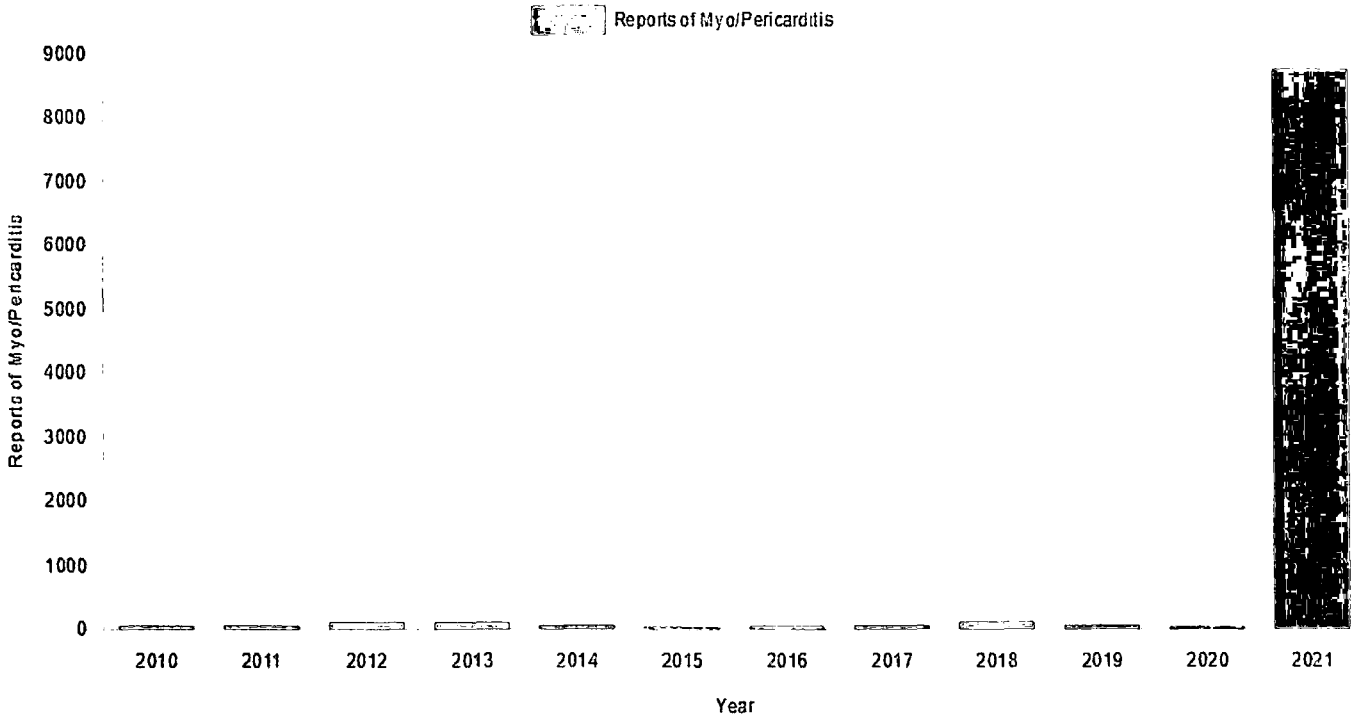
Through October 01, 2021



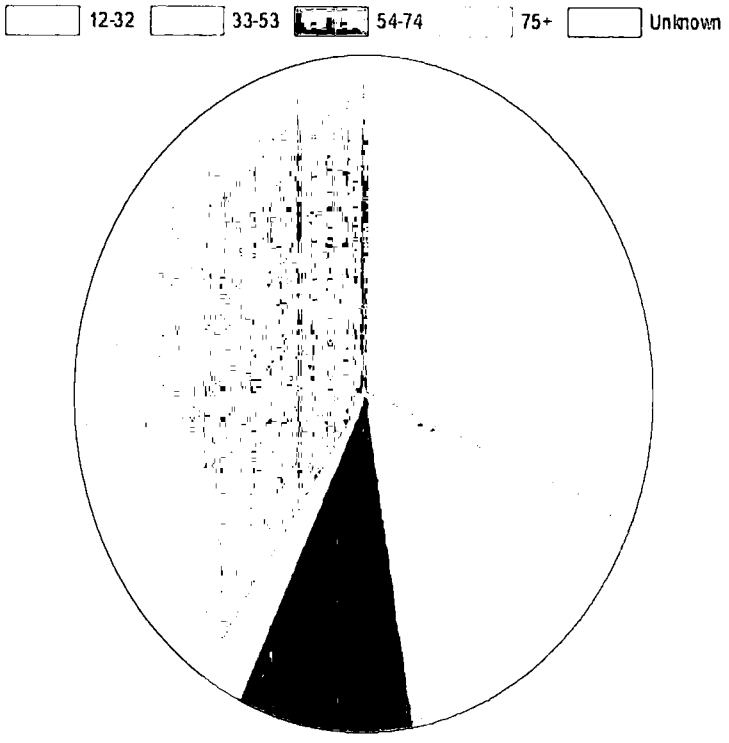
All Myo/Pericarditis Reported to VAERS Post COVID Vaccine by Dose



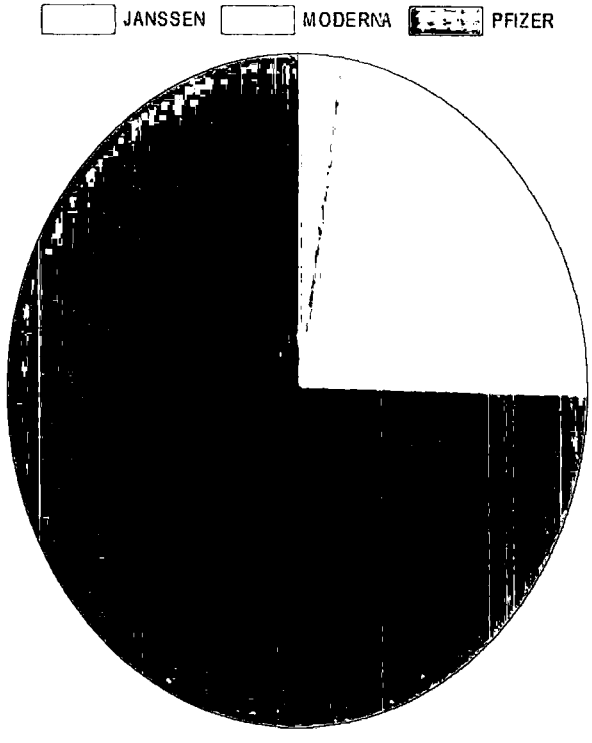
All Myo/Pericarditis Reported to VAERS by Year (all vaccines)



VAERS COVID Reports of Myo/Pericarditis by Age



VAERS COVID Reports of Myo/Pericarditis by Manufacturer



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